Attachment 1
Appendix of Exhibits

Volume I

TABLE OF EXHIBITS

COLLEGE of AMERICAN PATHOLOGISTS

November 11, 2020

Reference Number: 10219
CAP Number: 8729023
AU ID: 1690070

Michele Glinn, PhD
Avertest LLC d/b/a averhealth
Averhealth Laboratory
Suite A
2916 W. Marshall St
Richmond, VA 23230

EXPRESS MAIL

Dear Dr. Glinn:

The College of American Pathologists' (CAP) Accreditation Programs has received a complaint containing the following allegations:

1. Concern with regard to mass spectrometry confirmatory testing.
2. Failure to follow procedures as written.
3. Concerns regarding instrument calibrations.
4. Concerns regarding the review of quality control results.

The CAP's Accreditation Programs has been granted deeming authority under the Clinical Laboratory Improvement Amendments (CLIA). The CAP is, therefore, responsible for determining whether its accredited laboratories are providing testing that meets the applicable regulatory requirements for certification and is obligated to investigate immediately any complaint concerning an accredited laboratory.

Please provide the following items by **November 24, 2020** to my attention at the CAP's central office:

- A concern was raised in regard to mass spectrometry testing. The concerns pertain specifically to how quality controls, internal standards, defined cut-off and calibration data are interpreted, prior to the release of patient results. There are also concerns that practice does not follow laboratory procedures.

1. Provide a copy of the laboratory's mass spectrometry procedures for confirmatory drug testing on oral, urine and hair samples.
   a. Include detailed procedures that describe how calibrators, internal standards and quality control results are tested and interpreted, prior to releasing patient results.
2. Provide a copy of the Mass Spectrometry method performance validation summary for Cannabinoids (urine), Cocaine (urine, hair and oral fluid) and Morphine (hair and oral fluid).
   a. Include accuracy, precision, sensitivity, specificity, and defined cut-off for each analyte.

3. Provide documented evidence of weekly and monthly reviews of Cannabinoids, Cocaine and Morphine quality control results for the months of August, September and October 2020, as referenced in the following CAP checklist requirements.
   a. Include detailed records of corrective actions taken when controls/standard/calibration demonstrated low intensity or failed to meet defined ranges.

FDT.02060 Weekly QC Review **Phase II**

Quality control data are reviewed and assessed at least weekly by the laboratory director or designee to detect instrument malfunction or analytical system trends.

Evidence of Compliance:
✓ Records of QC review with follow-up for outliers, trends, or omissions

FDT.02080 Monthly QC Review **Phase II**

Quality control data are reviewed and assessed at least monthly by the laboratory director, including QC and blind QC records or summarized QC data to detect trends, and review of corrective actions taken by laboratory personnel.

NOTE: The laboratory director must be responsible for the overall QC program, which must include review at least monthly of QC analysis, QC evaluation and corrective actions taken, including appropriate records by laboratory personnel. The review of the quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

Evidence of Compliance:
✓ Records of QC review and follow-up for outliers, trends, or omissions

4. Provide copies of daily quality control, internal standards and patient run records, as indicated in the following CAP checklist requirements, for the following dates/analytes:
    - June 30, 2020 Cocaine and Cannabinoids
    - August 5, 2020 Cocaine and Cannabinoids
    - October 8, 2020 Morphine

FDT.22330 Daily QC **Phase II**

The written procedure requires that appropriate controls are extracted and analyzed with each batch of specimens.

NOTE: See General Quality Control section for specific controls required.

FDT.22430 Internal Standard **Phase II**

Internal standards are used as appropriate.

NOTE: An internal standard is not required for FDA-cleared/approved kits where an internal standard is not used. For a qualitative assay, the use of an internal standard is appropriate if sample preparation includes an extraction step(s), there is low or variable analyte recovery, and/or an accurate sample injection volume is important.

Evidence of Compliance:
✓ Written policy defining the use of the internal standard **OR**
✓ Written justification for not using an internal standard in assay

FDT.22830 LC Records **Phase II**

Specimen run order, chromatographic peak shape and retention time for calibrators, controls and unknowns are recorded and maintained for review.

FDT.22930 Analytical Data **Phase I**

The analytical data are presented to permit scientific review by the analyst of the data for calibrators, controls, and unknowns.

a. Include documentation of corrective actions taken if the controls, standards or calibration data did not meet defined acceptability criteria.

5. Provide instrument run results for all days that the sample assigned accession #11174895 was tested.
   a. Provide quality control, internal standard, calibration and patient data, that consists of specimen run order, chromatographic and peak shapes. The data should be presented in a manner that permits scientific review of all control, standard, calibration and patient data and how the laboratory interpreted the final result.
   b. Did the laboratory experience any issues when testing this sample? If yes, please explain the issue in detail and provide documentation to support the laboratory's response.
   c. Provide a copy of the final report for this sample.
   d. Provide corrective actions taken, as applicable.

6. Has the laboratory discovered false positive results on patients in 2020? If yes, provide completed root cause analysis for each encounter and corrective actions taken to prevent further issues.

7. Provide documentation demonstrating the manner in which the laboratory complies with the following CAP checklist requirement. Include the laboraotry's procedure and an example of the manner that concerns are documented, investigated and resolved.

*****REVISED**** ***06/04/2020***

GEN.20325 Employee and Patient Quality Communication **Phase II**

The quality management program includes a process for employees and patients to communicate quality and safety concerns to management.

NOTE: The investigation and analysis of employee and patient complaints and suggestions, with corrective or preventive action as appropriate, must be included in the laboratory quality management records.

Evidence of Compliance:

✓ Records of employee and patient complaints (if any) with appropriate follow up

8. During the last ten months, has the laboratory received any concerns regarding quality from employees, patients and/or providers? If yes, provide a detailed summary of each concern, how the concern was investigated and resolved.

9. Submit a signed Acknowledgement Form.

When we receive the requested documentation, an acknowledgement of receipt letter will be sent to the laboratory. After this information has been reviewed, the CAP Accreditation Programs will determine whether any further action is warranted.

You may forward your response by mail or e-mail to lliubin@cap.org. If you have any questions, please contact Loretta Liubinskas, Investigations Analyst at 800/323-4040, extension 7888. Thank you.

Sincerely,

Earle S. Collum, MD, Complaints and Investigations Committee Chair
CAP Accreditation Programs

ESC/ll/MAW

cc: Walter H. Henricks, MD, Chair, Commission on Laboratory Accreditation
Arthur M. Zebelman, PhD, Regional Commissioner
Loretta Liubinskas

COLLEGE OF AMERICAN PATHOLOGISTS
CAP ACCREDITATION PROGRAMS

ACKNOWLEDGEMENT FORM

Suggestions for Responding to an Investigation:

- For complaint investigations provide a summary statement addressing all allegations.
- Provide supporting documentation as requested. Designate key information on documents and avoid submitting excess pages when possible.
- Clearly label all supporting documentation by referencing allegation numbers, CMS D tags, other agency citations, CAP checklist requirements, or other attachment designations.
- To facilitate document imaging avoid the use of staples, page protectors, or binders, and submit single-sided documents.
- Responses may be sent by mail or commercial carrier. Email may be used if file sizes are less than 25 MB.

Acknowledgement Statement:

I attest that the laboratory's (Avertest LLC d/b/a averhealth Averhealth Laboratory, CAP # 8729023) responses and supplemental documentation for the College of American Pathologists have been reviewed and, to my knowledge, are complete and accurate.

Michele Glinn, PhD, Laboratory Director

_____

(signature and date)

Please complete this form and return it with your response to this investigation to:

Investigations Department
CAP Accreditation Programs
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750

AU ID # 1690070
Reference # 10219

COLLEGE of AMERICAN PATHOLOGISTS

MEMORANDUM

TO: Arthur M. Zebelman, PhD

FROM: Lena Portillo

DATE January 11, 2021

RE: Avertest LLC d/b/a Averhealth Laboratory, Richmond, VA
Reference Number. 10219
CAP Number 8729023
AU ID: 1690070

Please review the previous memo dated December 17, 2020, which is included behind this memo. Additionally, Dr. Zebelman's initial review comments have been printed and included just prior to the laboratory responses so that they may be read verbatim.

I have reviewed the additional documentation received from Avertest LLC d/b/a Averhealth Laboratory, Richmond, VA in response to our request for information relating to the complaint investigation. This complaint was received from a former employee The allegations are summarized below

Allegation #1: Concern regarding unacceptable quality assurance of mass spectrometry confirmatory testing

As discussed in the prior memo, there were numerous concerns raised regarding the quality assurance practices for mass spectrometry confirmatory testing. Via additional documentation request, the laboratory was asked to clarify QC practices and process as well as to provide corrective actions for several failed PT challenges, evaluation of significant bias, and additional information for several specifically noted test issues

The laboratory responded that they have had an exceptional inspection record and believe that the complainant was only seeking financial gain. The director states in the written response that the complainant never raised any concerns while employed and had, in fact, shared her eagerness to work with the team the day before her resignation. This is an interesting statement, as the complainant provided the email she sent two days prior to resigning and it outlines in detail numerous quality concerns. This perhaps indicates a lack of communication between Dominique Delagnes (the COO to whom the message was sent) and the Medical Director, Dr. Glinn (who is responding to the allegations)

In response to the request to submit the corrective actions for failed UDC and ORF survey challenges, the PT Exception Investigation Forms were provided. Overall, the forms do not address a root cause for failures, listing conclusions such as "repeat acceptable, unclear why low initially" and "all acceptable upon repeat", with no investigation into the reason for the incorrect initial results Several summaries state that repeats with new calibrators, or with a different IS were acceptable, with no indication of whether patient results may have been affected when the prior calibrators or IS were in use Only one PT investigation from for the UDC survey included actual corrective actions and investigation, and this was performed

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after the laboratory became aware of the complaint investigation Specific details noted by Joan Kosiek include:

- UDC-A 2019 analysis was completed and signed off by M Glinn on 2/15/19 however, the report states "staff training was completed on 3/6/19". This was documented as being done three weeks after her original signoff of the investigation
- UDC-A 2020 Samples 01-MDMA, 06-oxycondone, 10- Benzoylecgonine – values submitted were at least half of the expected response – recalibrated and repeated – all accepted; urine pH 02, 06 and specific gravity UDC 1,5,6,9 all very low- laboratory went from manual reading to an instrument, technical errors.
- OFD-A-20202 Nordiazepam – changed the internal standard, methadone – reported as neg – expected pos – laboratory stated, "Just below cutoff" The FDT survey has cutoffs that the laboratory must attain.
- OFD-B-2020 Samples 6 hydromorphone, 08 PCP, 09 Temazepam – laboratory stated "temazepam is extremely variable, compound is not stable"

In response to the request for assessing the significant bias in the UDC survey for specific gravity, creatinine, pH, morphine, 6-AM and delta-9-THC-COOH results, the laboratory provided their quality management policy and the most recent instrument correlation. Per the laboratory, bias is evaluated via the twice-yearly instrument comparisons, AMR verifications, and qualitative cut-off verifications They do not directly address the significant bias in their survey results. As noted by Joan K , one of the questions on the PT Exception Form asks – Does review of past PT results indicate evenly distributed date without bias? The laboratory responded "Yes". A review of the bar graphs from the past three cycles of survey challenges clearly shows bias in one direction for numerous analytes This remains unaddressed.

The laboratory also provided their PT assessments for hair samples, which are ordered from LGC. The written response states that no results were unacceptable, however, the June 2020 survey shows 4 "questionable" results and 1 unacceptable result for cocaine. The September 2020 survey shows 1 "questionable" result. There are no comments or follow-up included with the reports

As previously discussed, I believe that this allegation is **substantiated** The associated checklist items include COM.01700 – PT evaluation and GEN 13806 QM Program.

I do not believe that the laboratory has appropriately addressed this allegation and feel follow-up via on-site inspection is warranted

Allegation #2: Failure to follow procedures as written.

As discussed in the prior memo, the laboratory's procedures are largely acceptable but they are not being followed as written. As is seen in the narratives of the other allegations, the laboratory does not appear to be following their QC and calibration policies It was noted by Joan K during her review of the substantial amounts of data that there were instances where they did not obtain results for calibrator one or two and reported results less than the recovered calibrator, or where 3 of 8 calibrators were excluded but the run was reported. The written laboratory response indicates they have no record of reporting under these circumstances, and unfortunately I do not have the specific pages without imposing upon Joan to look through the massive amounts of data again Regardless, the laboratory is also

not evaluating their survey results with a root cause analysis, as required by policy, nor do the policies address the "magic" that is referenced in the chat transcripts provided by the complainant referencing the QC and calibrator manipulations used to report results.

For these reasons, and as previously discussed, I believe that this allegation is **substantiated**. The associated checklist item is COM.10300 – Knowledge of Policies and Procedures

I do not believe this has been resolved and suggest following up on laboratory practices via onsite inspection.

Allegation #3: Concern regarding the manipulation of instrument calibrations.

The laboratory was asked to provide the policy for acceptance of calibration curves and to include specific examples where points are excluded They were also asked to submit examples for the use of historical control values when there is disparity between the internal standard and control/calibrator values. The QC policy was provided, which addresses calibrations and acceptability criteria. Attachments E1 to E3 reflect examples of calibration curves with points excluded. Attachments F1 and F2 are examples of the use of historical data.

Per the laboratory written response, historical QC data is only acceptable when the following criteria are met.

I. The internal standard recovery of a calibrator or control is very low, indicating injection failure or prep error, that calibrator or control will be excluded but not both;
II. The calibration curve is valid, and
III. The internal standard recoveries and chromatography for the unknowns are acceptable

Please review this data as I am not knowledgeable enough to provide comment on the acceptability

I believe that this allegation is likely **substantiated,** as previously discussed, and should be further investigated on-site. Associated checklist items include FDT.02002 – QC Confirmation of Acceptability, FDT.02030 – QC Acceptance Criteria, and FDT 02715 QC Corrective Action

Allegation #4: Concern regarding the review of quality control results

The laboratory was asked to provide an explanation of the process for manual integration of chromatic peaks and explain the approval process. Five examples were included, with an explanation that the most common reasons to manually integrate is excessive tailing, removal of a shoulder peak, or a retention time shift that is specific to a sample. Per the laboratory, review is performed by two certifying scientists. A third reviewer may be requested if any points are unclear Attachments D2.1 – D6.3 are examples of manual integration, please review these for acceptability.

The laboratory was asked to clarify run repeat criteria, as well as the process for repeat testing The QC Policy contains a section addressing Repeat Analyses. Individual or batched

samples may be repeated. Poor chromatography, unresolved standards, and instrument issues are criteria for repeat, as well as QC or calibration data being out for multiple compounds in a batch. Attachments F1-F3 show samples which were re-run.

The laboratory was asked about the QC policy which states that when QC is not acceptable, results are not release It does not state that negative results are repeated. Per the laboratory, if the internal standard (IS) is present, the certifier may release negative results as this means that the extraction worked. I do not believe this is an acceptable practice under any circumstance, as it negates the purpose of positive controls.

In regard to questions of who is performing the QC review, and for specific corrective actions for comments noted on instruments "Venom" and "Poison Ivy", the laboratory explains that the Director is performing these reviews They also state that the issues noted with instruments "Venom" and "Poison Ivy" have documented corrective action The laboratory states this is included as attachment G1; however, there is no attachment G1.

I believe that this allegation is **substantiated**. The associated checklist items include FDT.02002 – QC Confirmation of Acceptability, FDT.02030 – QC Acceptance Criteria, and FDT.02715 QC Corrective Action.

Finally, the laboratory was asked about a document submitted regarding retest result variances. They clarify that this is from a customer education document and provide several references. I think this question can be resolved without further action

I suggest presentation to the Accreditation Committee for consideration of a Non-Routine Inspection and/or probation. I believe the laboratory needs an experienced inspector who can educate them, as they do not seem to understand the issues.

Please review these documents and recommend our next action within five days of your receipt of this memo
You may forward your response by email to lportil@cap.org. If you have any questions, please contact me at 800/323-4040 extension 7349. Thank you.

Enclosure

cc. Meggen A. Walsh, DO, FCAP

COLLEGE of AMERICAN PATHOLOGISTS

MEMORANDUM

TO Arthur M Zebelman, PhD

FROM. Lena Portillo

DATE· December 17, 2020

RE Avertest LLC d/b/a Averhealth Laboratory, Richmond, VA
Reference Number 10219
CAP Number. 8729023
AU ID 1690070

I have reviewed the documentation received from Avertest LLC d/b/a Averhealth Laboratory, Richmond, VA in response to our request for information relating to the complaint investigation This complaint was received from Dr Sarah Riley, a former employee at the laboratory, with 12+ years of experience She worked at the laboratory as a Technical Director for six weeks and left because she was uncomfortable with the practices she observed

The documentation was reviewed by Joan Kosiek, the Technical Analyst for the FDT program, in consultation with Dr Zebelman Due to the serious nature of these allegations, they have recommended a non-routine inspection be performed The allegations are summarized below

Allegation #1: Concern with regard to mass spectrometry confirmatory testing

The complainant, Dr Riley, expressed concerns regarding laboratory confirmatory drug testing Per Dr Riley, QCs and calibrations for LC-MS hair, urine, and oral fluid testing are frequently out Manipulations such as excluding QC data, calibrator data, or applying historical QC and/or calibrator values are used so that testing may be reported Examples of staff chats were provided, where staff are asked to "work their magic" to get QCs in Dr Riley describes multiple IS and regression lines being used for each analyte, with no validation or comparison to determine if the results are equivalent In an email sent to the COO, Dr Riley provides another scenario where the morphine results on a hair batch were released, even though all but calibrator 6 and the high calibrator were out. The email goes on to state that she is very uncomfortable with the practices she has observed and, if she were called in as an expert witness, she would be able to "tear the runs to pieces".

The laboratory was asked to explain their mass spectrometry confirmatory process, describing in detail how calibrators, internal standards (IS), QC, and patient results are interpreted Evidence of weekly and monthly QC review were requested They were asked for copies of procedures as well as validation summaries for cannabinoids (urine), cocaine (urine, hair, oral fluid), and morphine (hair, oral fluid) Finally, the laboratory was asked to describe any false positives in 2020 and whether concerns have been received

The Technical Analyst over the FDT checklist, Joan Kosiek, was asked to review the documentation Thousands of pages were submitted, consisting primarily of raw data Joan

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noted that the individual test procedures for each drug were well written, but identified several discrepancies, as follows

- The Quality Control policy includes contradictory statements and unacceptable practices There are also many instances where policy does not match practice Here are some specific concerns
    - The policy states that the lower limit of reporting may be at or above the lowest calibrator There are instances where the laboratory did not obtain results for calibrator 1 or 2 (low levels) and reported values less than the recovered calibrator value
    - The policy states that no more than 25% of the total number of data points per curve may be excluded without the director/designee review There are instances of 3 out of 8 calibrators not being included in the curve This indicates unstable calibration.
    - The policy states that if the Internal standard (IS) area of the unknowns is similar to that of the calibrators, but the QC IS area is different, exclude those QCs and proceed with analysis If both QC sets need to be excluded, use historical QCs. If the IS area of the unknowns is similar to that of the QCs but the calibrators are different, use a historical calibration curve but keep the current QCs They are manipulating the value of the IS to try and accommodate poor responses and accept runs or a patient sample without understanding why there are discrepancies Further, they have adopted acceptance criteria that has no scientific foundation in good practice There is no "magic" to be worked in patient samples The lab either has acceptable in-process QC principles or it does not
    - The policy states that quality control can be reviewed monthly by the director or designee Per FDT 02080- the Director must review monthly QC
    - The policy states that if QC is not acceptable, no positive results may be released It does not state that negative results are held for repeat analysis
    - In the process of evaluating a screen positive result, repeat testing is performed If the second test is within 15r % of the first result but below the cutoff, it is reported as negative It should be repeated a third time.
- Cutoffs for cocaine and benzoylecgonine change from 5 ng/ml (April 6th) to 1 ng/ml (June 17th) for oral fluid It is unclear what this is based on
- Lab Director QC Review 7-26-19 to 8-15-20 for Instrument "Venom" states "Benzos out for OF, Instrument "Poison Ivy": "Values for hair not accurate " There are no corrective actions noted
- The laboratory claims that "Retest Result Variances" are expected to differ by +/- 20% "The +/- 20% variance is the standard of major forensic drug testing accrediting and professional societies including CAP-FDT, COLA and AAFS" Per FDT 02030, which applies to Quality Control values and not patient samples "The criteria for acceptance/rejection of quantitative QC results should at a minimum include the rejection of QC results that exceed a pre-determined range of the established control mean It is commonly accepted that this range be no more than ± 20% for urine assays and no more than ± 30% for other specimen matrices."

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Regarding the request to evaluate false positives, the written laboratory response discusses two false positives identified on July 21, 2020, which where attributed to carryover Per the laboratory, this is very rare and upon identifying the error the Director conducted training to prevent recurrence In regard to whether the laboratory has received any concerns, they indicated that one customer raised a concern regarding "slight" differences between initial

confirmation results and subsequent retest results Per the laboratory, some samples that tested as positive near the cutoff repeated as negative due to analytical variance and sample degradation Educational materials were provided to the customer to explain this, and a meeting was also conducted

I believe this allegation will likely be **substantiated** and recommend a non-routine inspection to investigate further.

Allegation #2: Failure to follow procedures as written

The complainant alleged that procedures are not followed regarding acceptability of run data. The laboratory was asked to provide their mass spectrometry procedures for confirmatory drug testing on oral, urine, and hair samples, as well as calibrator and control procedures As described in detail above, the Quality Control policy includes contradictory statements and there are also many instances where policy does not match practice Several instances were noted by the FDT reviewer where the policy states that the lower limit of reporting may be at or above the lowest calibrator, but the laboratory reported values less than the recovered calibrator value Additionally, the policy states that no more than 25% of the total number of data points per curve may be excluded without the director/designee review, but there are instances of 3 out of 8 calibrators not being included in the curve The policies also include unacceptable practices, such as designee review of monthly QC and manipulation of QC and calibrators to accept runs

I believe this allegation will likely be **substantiated** and recommend a non-routine inspection to investigate further

Allegation #3: Concerns regarding instrument calibrations

The complainant alleged that calibrators frequently fail, so historical values are used The laboratory also reports positive results above the lowest acceptable calibrator even when the lower calibrators fail. As noted by the complainant and the FDT reviewer and discussed in allegation #1, this is not an acceptable practice. They are manipulating the value of the IS to try and accommodate poor responses and accept runs and patient samples without understanding why there are discrepancies Further, they have adopted acceptance criteria that has no scientific foundation in good practice

I believe this allegation will likely be **substantiated** and recommend a non-routine inspection to investigate further

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Allegation #4: Concerns regarding the review of quality control results

As discussed in allegation #1, the complainant alleged that QC frequently fails, and that data is manipulated so that QC can be accepted Historical QC is sometimes used if run QC does not pass Screenshots were provided of an internal staff chat where numerous runs are requested to be re-reviewed and for staff to "work their magic" so the QC passes Per the FDT Technical Analyst, the laboratory is abusing the value of QCs and how to properly use calibrators It shows a fundamental lack of understanding of the use of IS and how to evaluate MS data

I believe this allegation will likely be **substantiated** and recommend a non-routine inspection to investigate further.

As discussed above, given the serious nature of these concerns **it is recommended that a non-routine inspection be performed** to delve deeper into this laboratory's practices. I have reached out Katie Bronoski, who believes that this inspection could be scheduled in January and would include a specialty inspector and a staff inspector

Please review these documents and recommend our next action within five days of your receipt of this memo This case will not be closed until a non-routine inspection is performed and reviewed

You may forward your response by email to lportil@cap org. If you have any questions, please contact me at 800/323-4040 extension 7349 Thank you

Enclosure

cc: Meggen A. Walsh, DO, FCAP

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Lena Portillo (s)

From: azebelman@gmail.com
Sent: Sunday, January 10, 2021 10:42 PM
To: Lena Portillo (s), Joan Kosiek (s); Kelly Hock (s); Michael Peat PhD; R.H. Barry Sample PhD
Cc: Arthur M Zebelman PhD
Subject: FW: CAP Additional Documentation Request, Ref 10219
Attachments: 00 - Response_20210104.pdf; December 22.pdf; Averhealth Laboratories CAP No 8729023 and Complaint 10219 Review by Dr Zebelman 1-10-2021 docx

Please find attached my opinions (in red in the Word document) relative to the responses of Dr. Michele Glinn of Averhealth Laboratory to Complaint #10219. I want to thank Joan Kosiek for her painstaking review of Dr. Glinn's responses. This laboratory has many quality assurance issues in the areas of quality control and proficiency testing. I believe they need to be put on probation and required to institute more thorough follow up and resolution of their QA issues.

I would greatly appreciate Drs. Peat and Sample taking a look at the attached material.

Arthur M. Zebelman, Ph.D.
FDT Commissioner

From: Lena Portillo (s) <LPORTIL@CAP.ORG>
Sent: Tuesday, January 5, 2021 7:04 AM
To: Arthur M Zebelman PhD <azebelman@gmail.com>
Cc: Joan Kosiek (s) <jkosiek@cap.org>; Kelly Hock (s) <khock@cap.org>
Subject: FW: CAP Additional Documentation Request, Ref 10219

Hello Dr. Zebelman,

Please find attached the laboratory response to the additional documentation request that was sent (also attached). Can you kindly review and provide your thoughts/comments? Joan K. will also be looking through the documentation. My initial thought is that the director has not really addressed anything nor does she see a problem.

Thank you for all your help, it is much appreciated!

Best,

Lena Portillo, MT(ASCP)
Investigations Analyst, CAP Accreditation Programs
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PT #1 – Submit detailed corrective actions for all unacceptable proficiency testing results from the 2019 and 2020 UDC and ORF survey challenges.

Attached are the UDC LIFs and OFD LIFs for the corrective action summaries for all unacceptable
proficiency testing results from the 2019 and 2020 UDC and OFD survey challenges. In all cases, the completion of the CAP LIF yielded satisfactory results.
Attachment A1, UDC LIFs
Attachment A2, OFD LIFs
Attachment A3, LN6-B LIF

As Joan Kosiek states in her email of January 5, 2021 at 10:22 AM, this laboratory has numerous problems with proficiency testing in all of the matrixes they test – urine, hair and oral fluid. They have failed to find some drugs that are present and most frequently, their quantitation is inaccurate. The follow up is incomplete and most often just stops if they can get results that are acceptable, without identifying a root cause of the issue. I suspect this is in part because they are pushing their analyses to try to cover too large a dynamic range of concentrations which means that they have non-linear response curves requiring complex polynomial regressions and a great deal of hands-on manipulations make things work. **The laboratory does not seem to have a problem with false positive results, but their quantitation is at times unacceptable and they do not seem to take the timely resolution of such problems seriously enough.**

PT #2 – Submit the policy for evaluation of significant bias shown in quantitative results in the UDC survey for specific gravity, creatinine, pH, morphine, 6-AM and delta-9-THC-COOH results.

Attached is our Quality Management Policy and most recent instrument comparison. As described in the Quality Management Policy, bias is evaluated via twice-yearly instrument comparisons, analytical measurement range verifications, and qualitative cutoff verifications. The most recent instrument comparisons were completed in November 2020, which show that all instruments running the same method correlate (i.e., no issues with any of the assays).
Attachment B1, Quality Management Policy
Attachment B2, November 2020 Instrument Comparison

The Director misunderstood this question and needs to again consider the issue. The question refers to the quantitative bias demonstrated in several proficiency testing challenges over time with reported result biased low (usually) or high relative to the method mean values.

PT #3 – Submit the alternative PT assessments performed on hair samples.

Enclosed are results for hair testing proficiency results. These are ordered from LGC, which is the most widely used proficiency testing program for hair testing. No results were unacceptable.

Attachment C1, Hair Proficiency Test Results for June 2020
Attachment C2, Hair Proficiency Test Results for September 2020

The laboratory's 22 June 2020 result for cocaine was characterized as "unsatisfactory" and the results for codeine, morphine, 6-monoacetyl-morphine and methyl-amfetamine were classified as "questionable." There is no provided follow up.

The provided 01 September 2020 report indicates that the delta-9-THC result was "questionable." Again, no follow up is provided.

Once again, there we no false positive findings, but the quantitation is frequently problematic and there appears to be no documented follow up to the issues.

QC #1 – Provide policy for manual integration of chromatographic peaks along with five examples and explain the approval process for such occurrences.

Attached is the LC-MS/MS Quality Control Policy (Attachment D1), which includes policy for manual integration and acceptance of calibration curves.
Enclosed are five examples of manual integration. These examples show the peaks as integrated by the instrument processing program, as well as after manual integration for comparison. The most common reasons to manually integrate is excessive tailing, to remove a shoulder peak, or a retention time shift that is specific to one sample.

The instrument data approval process requires the review of two certifying scientists, a first and second reviewer. The first reviewer ensures all integrations are correct and that calibration and quality control data are acceptable. If data are unacceptable, the first reviewer will make a note for the second reviewer. The second reviewer, who has more training and experience than the first reviewer, re-reviews the analyses of first reviewer, approves all data, requeues any unacceptable specimens or batches, and releases results for reporting. The second reviewer may request a third review if any points are unclear. The third review is conducted by a supervisor or the Lab Director. All affected sample(s) are re-prepped and rerun when the calibration or QC data is out, or there is no internal standard present in sample(s) or in the controls.

Attachment D1, LC-MS/MS Quality Control Policy
Attachments D2.1 to D6.3, Examples of Manual Integration

When the QC policy has to provided for 3 certifying reviews, I submit there is a problem. Again, I believe they are trying to push their technology beyond what it is capable of. There is no problem *per se* of manual integration, but one example they provide of the integration of specimen 12427380-211 is in my opinion, unacceptable. There is a very large shoulder peak that manual integration would likely not correct. The QC SOP needs to provide for a means to judge when a should peak can be corrected by manual integration and when it cannot.

QC #2 – Provide the policy for acceptance of calibration curves including specific examples where points are excluded.

The policy for calibration curve acceptance is contained in Attachment D1. Points may be excluded if omission improves the calibration fit.

Attachment E1 to E3, Examples of Calibration Curve with Points excluded (Open Circles Reflect Excluded Data Points)

QC #3 – Submit examples of use of historical quality control values or calibrations when there is disparity between the internal standard and the control/calibrator values.

Attachments F1 and F2 provide examples of the use of historical data. The use of historical data is rare and only permitted when analytically appropriate. Analysts are trained that the use of historical data is only acceptable when the following three conditions are met:
i) the internal standard recovery of a calibrator or control is very low, indicating injection failure or prep error, that calibrator or control will be excluded, but not both;

ii) the calibration curve is valid, and

iii) the internal standard recoveries and chromatography for the unknowns are acceptable.
Consistent with industry practices, when the above three conditions hold, historical QC data is used for the acceptance of the run.
For verification, when an unknown sample has unacceptable internal standard recovery, it is always re-prepped and re-analyzed and when there is no internal standard in any of the calibrators, controls or unknowns, the run is re-prepped and repeated. Attachment F3 provides a snapshot of a log that shows where samples were re-ran due to QC issues or no internal standard.
Attachment F1 to F2, Examples of Historical Quality Control Data
Attachment F3, Specimen Re-run Log Snapshot

I do not understand what they mean when they say they may use historical quality control data. As I understand the phrase, which I have never seen used before, they somehow use QC data from a run different from that which they are assessing. I hope I am misunderstanding what they are suggesting. Please ask for clarification.

Repeat Testing #1 – Clarify the criteria requiring a run to be repeated.
The LC-MS/MS Quality Control policy (Attachment D1) contains a section addressing Repeat Analyses. Individual samples or entire batches may be repeated. Samples are batched together per confirmation method, which often contain multiple drug classes. When a batch is run, one sample may need one drug class to be tested, while another sample is tested for a different drug class. The entire batch is repeated if the chromatography is poor, the internal standards are not resolved, if there is an instrument issue, or the quality control or calibration data is out for multiple compounds in a batch. When the data presents an issue for a single compound (e.g., morphine), while the data for all other compounds are acceptable, only the samples with

problematic single compound are repeated and the results for other samples with acceptable data are released.

This is probably OK.

Repeat Testing #2 – Explain the process for repeat testing. The policy states that if a QC is not acceptable, no positive results may be released. It does not state that negative results are held for repeat testing.

When reviewing data, the certifier first determines is if the internal standards are present and recovery is acceptable. If the internal standard is not detectable for a given sample, that sample is always re-queued, re-prepped, and reanalyzed (see response to QC #1). When the internal standard is present, the extraction worked; therefore, samples may be determined to be negative for the drugs examined and the results released.

This is a dangerous practice and risks false negative reported results, particularly if a deuterated internal standard for all of the drugs in question is not being used.

Per FDT.02080 – The Director (not designee) must review monthly QC. Submit evidence of monthly review of quality control results and maintenance/equipment records by the director (not designee) for December.

While I was the Laboratory Director, I always reviewed the quality control results weekly and maintenance/equipment logs at least monthly. These reviews were not conducted by a designee. The Laboratory Director Review form is used for both weekly quality control data review, as well as monthly equipment log reviews. On September 14, 2020, Sarah Riley joined Averhealth as the Laboratory Director and I assumed the role of Clinical Consultant. During this transition, I offered to perform the reviews for a few additional weeks to afford Sarah Riley time to transition into the Laboratory Director role. Sarah Riley agreed to begin performing all reviews in October; however, she did not complete this responsibility. The only lapse in the review logs by the Laboratory Director occurred during the brief five-week period from October 10, 2020 to November 3, 2020, while Sarah Riley was the Laboratory Director. During this time period Sarah Riley failed to complete her required duties. Upon Ms. Riley's abrupt and unexpected departure, I resumed the Laboratory Director role and have since retroactively completed the reviews for this five-week time period to bring all reviews current and continue to complete weekly and monthly reviews on a timely basis.

Attachments G1 to G3, provide the December review of quality control results and maintenance/equipment records for December to date.

This is OK.

Lab Director QC Review 7-26-19 to 8-15-20 for instrument "Venom" states Benzos out for OF; Instrument "Poison Ivy" values for hair are not accurate. Submit corrective action taken.

This statement refers to the log sheet data entry error. Quality control data is manually tracked. The data entry error was subsequently addressed when I corrected the out-of-place values. This correction was documented in the Laboratory Director review of 12-4-20, Attachment G1.

This is OK.

Laboratory states that "Retest Results Variances" are expected to differ by +/-20%. FDT.02030 applies to criteria for acceptance/rejection of quantitative QC results and not patient samples. Provide supportive evidence for this statement.

This statement was part of a customer education piece that explains quantitative differences for a specimen tested twice with time lapse between tests.

This is OK.

COLLEGE of AMERICAN PATHOLOGISTS

December 22, 2020

Reference Number 10219
CAP Number 8729023
AU ID 1690070

Michele Glinn, PhD
Avertest LLC d/b/a Averhealth Laboratory
Suite A
2916 W Marshall St
Richmond, VA 23230

Dear Dr Glinn

The College of American Pathologists' (CAP) Accreditation Programs has reviewed your responses and documentation of corrective action for this investigation We appreciate the time you and your laboratory have spent in preparing these documents However, additional information is needed to facilitate our evaluation

Please submit the following items

- Several proficiency testing challenges show unacceptable results or significant bias
    - Submit detailed corrective actions for all unacceptable proficiency testing results from the 2019 and 2020 UDC and ORF survey challenges
    - Submit the policy for evaluation of significant bias shown in quantitative results in the UDC survey for specific gravity, creatinine, pH, morphine, 6-AM and delta-9-THC-COOH results
    - Submit the alternative PT assessments performed on hair samples
- The Quality Control policy includes unacceptable practices. For example, the policy states that if the Internal standard (IS) area of the unknowns is similar to that of the calibrators, but the QC IS area is different, exclude those QCs and proceed with analysis If both QC sets need to be excluded, use historical QCs. If the IS area of the unknowns is similar to that of the QCs but the calibrators are different, use a historical calibration curve but keep the current QCs This is data manipulation to accommodate poor responses and accept runs or a patient sample without understanding why there are discrepancies
    - Provide the policy for manual integration of chromatographic peaks along with five examples and explain the approval process of such occurrences
    - Provide the policy for acceptance of calibration curves including specific examples where points are excluded
    - Submit examples of use of historical quality control values or calibrations when there is disparity between the internal standard and the control/calibrator values
- There are instances where practice does not follow the QC policy For example, the policy states that the lower limit of reporting may be at or above the lowest calibrator. There are instances where the laboratory did not obtain results for calibrator 1 or 2 and reported values less than the recovered calibrator value Additionally, the policy states that no more than 25% of the total number of data points per curve may be excluded without the director/designee review There are instances of 3 out of 8 calibrators not being included in the curve, indicating unstable calibration
    - Clarify the criteria requiring a run to be repeated

    - Explain the process for repeat testing The policy states that if QC is not acceptable, no positive results may be released It does not state that negative results are held for repeat analysis
- Per FDT 02080- the Director (not a designee) must review monthly QC Submit evidence of monthly review of quality control results and maintenance/equipment records by the director (not designee) for December.
- Lab Director QC Review 7-26-19 to 8-15-20 for Instrument "Venom" states "Benzos out for OF, Instrument "Poison Ivy" "Values for hair not accurate " Submit the corrective actions taken
- The laboratory states that "Retest Result Variances" are expected to differ by +/- 20% "The +/- 20% variance is the standard of major forensic drug testing accrediting and professional societies including CAP-FDT, COLA and AAFS". FDT 02030 applies to the criteria for acceptance/rejection of quantitative QC results and not patient samples Please provide supportive evidence for this statement
- Submit the signed Acknowledgement Form

Please provide this information by **January 4, 2021** to my attention at the CAP's Northfield office We will send an acknowledgement of receipt letter to the laboratory upon receiving the required documentation

You may forward your response by mail or e-mail to lportil@cap.org If you have any questions, please contact me at 800/323-4040 ext 7471. Thank you

Sincerely,

Lena Portillo, MT(ASCP)
Investigations Analyst
CAP Accreditation Programs

cc Arthur M. Zebelman, PhD, Regional Commissioner
Meggen A Walsh, DO, Member, FCAP, Complaints & Investigations Committee

CXADLDOC

averhealth

Received
JAN 04 2021
LAP

January 4, 2021

Lena Portillo, MT (ASCP)
Investigations Department
CAP Accreditation Department
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750

Subject: Reference Number: 10219, CAP Number: 8729023, AU ID: 1690070

Dear Ms. Portillo:

Enclosed herein is the additional information you requested to complete the evaluation.

Many of the responses reference the Quality Management Policy (Attachment B1) and the LC-MS/MS Quality Control Policy (Attachment D1). CAP initially evaluated these polices in 2016 for our original CAP accreditation inspection and on two additional separate occasions for follow-up inspections. These same polices have also been inspected by CLIA, the State of New York, and two Pathologists from Washington University in St. Louis. These policies have passed all inspections, received complimentary comments on multiple occasions, and align with the polices of other CAP-FDT accredited laboratories.

We have tremendous respect for the CAP evaluation process and the need to ensure confidentiality of a complaint. In this case, the veil of confidentiality was pierced by Sarah Riley, the complainant, who publicly disclosed, post resignation from Averhealth, that she believed we have quality issues and was submitting a complaint to CAP. It is perplexing that Sarah Riley never once raised any concerns while working for Averhealth and just one workday prior to abruptly resigning, Sarah Riley shared how much she looked forward to working with the team. Sarah Riley disregarded the principles of ethical conduct for the toxicology profession by violating confidentiality, honesty, and personal integrity and by discrediting the profession.

While the allegations of data manipulation and lack of adherence to policy are alarming, we believe that Sarah Riley hastily arrived at these conclusions to support a bogus lawsuit for personal financial gain. For example, the request for additional information states the laboratory did not obtain results for calibrator 1 or 2, reported values less than the recovered calibrator value, and there are instances of 3 out of 8 calibrators not being included in the curve, indicating unstable calibration. We have no records of reporting results under these circumstances. If such

data was provided, it would be essential to evaluate the context because not all results obtained in an instrument are reported and policies allow for supervisor review of select data on a case-by-case basis. We know that during Sarah Riley's brief six weeks as our Laboratory Director, she failed to fulfill several assigned job duties, including establishing familiarity with policies.

We believe that upon your review of the information enclosed herein you will arrive at a finding of Not Substantiated. We welcome any suggestions you may have and are available to answer any questions that remain open after your review of the enclosed information.

PT #1 – Submit detailed corrective actions for all unacceptable proficiency testing results from the 2019 and 2020 UDC and ORF survey challenges.

Attached are the UDC LIFs and OFD LIFs for the corrective action summaries for all unacceptable proficiency testing results from the 2019 and 2020 UDC and OFD survey challenges. In all cases, the completion of the CAP LIF yielded satisfactory results.

Attachment A1, UDC LIFs
Attachment A2, OFD LIFs
Attachment A3, LN6-B LIF

PT #2 – Submit the policy for evaluation of significant bias shown in quantitative results in the UDC survey for specific gravity, creatinine, pH, morphine, 6-AM and delta-9-THC-COOH results.

Attached is our Quality Management Policy and most recent instrument comparison. As described in the Quality Management Policy, bias is evaluated via twice-yearly instrument comparisons, analytical measurement range verifications, and qualitative cutoff verifications. The most recent instrument comparisons were completed in November 2020, which show that all instruments running the same method correlate (i.e., no issues with any of the assays).

Attachment B1, Quality Management Policy
Attachment B2, November 2020 Instrument Comparison

PT #3 – Submit the alternative PT assessments performed on hair samples.

Enclosed are results for hair testing proficiency results. These are ordered from LGC, which is the most widely used proficiency testing program for hair testing. No results were unacceptable.

Attachment C1, Hair Proficiency Test Results for June 2020
Attachment C2, Hair Proficiency Test Results for September 2020

QC #1 – Provide policy for manual integration of chromatographic peaks along with five examples and explain the approval process for such occurrences.

Attached is the LC-MS/MS Quality Control Policy (Attachment D1), which includes policy for manual integration and acceptance of calibration curves.

Enclosed are five examples of manual integration. These examples show the peaks as integrated by the instrument processing program, as well as after manual integration for comparison. The most common reasons to manually integrate is excessive tailing, to remove a shoulder peak, or a retention time shift that is specific to one sample.

The instrument data approval process requires the review of two certifying scientists, a first and second reviewer. The first reviewer ensures all integrations are correct and that calibration and quality control data are acceptable. If data are unacceptable, the first reviewer will make a note for the second reviewer. The second reviewer, who has more training and experience than the first reviewer, re-reviews the analyses of first reviewer, approves all data, requeues any unacceptable specimens or batches, and releases results for reporting. The second reviewer may request a third review if any points are unclear. The third review is conducted by a supervisor or the Lab Director. All affected sample(s) are re-prepped and rerun when the calibration or QC data is out, or there is no internal standard present in sample(s) or in the controls.

Attachment D1, LC-MS/MS Quality Control Policy
Attachments D2.1 to D6.3, Examples of Manual Integration

QC #2 – Provide the policy for acceptance of calibration curves including specific examples where points are excluded.

The policy for calibration curve acceptance is contained in Attachment D1. Points may be excluded if omission improves the calibration fit.

Attachment E1 to E3, Examples of Calibration Curve with Points excluded (Open Circles Reflect Excluded Data Points)

QC #3 – Submit examples of use of historical quality control values or calibrations when there is disparity between the internal standard and the control/calibrator values.

Attachments F1 and F2 provide examples of the use of historical data. The use of historical data is rare and only permitted when analytically appropriate. Analysts are trained that the use of historical data is only acceptable when the following three conditions are met:

i) the internal standard recovery of a calibrator or control is very low, indicating injection failure or prep error, that calibrator or control will be excluded, but not both;

ii) the calibration curve is valid, and
iii) the internal standard recoveries and chromatography for the unknowns are acceptable.

Consistent with industry practices, when the above three conditions hold, historical QC data is used for the acceptance of the run.

For verification, when an unknown sample has unacceptable internal standard recovery, it is always re-prepped and re-analyzed and when there is no internal standard in any of the calibrators, controls or unknowns, the run is re-prepped and repeated. Attachment F3 provides a snapshot of a log that shows where samples were re-ran due to QC issues or no internal standard.

Attachment F1 to F2, Examples of Historical Quality Control Data
Attachment F3, Specimen Re-run Log Snapshot

Repeat Testing #1 – Clarify the criteria requiring a run to be repeated.

The LC-MS/MS Quality Control policy (Attachment D1) contains a section addressing Repeat Analyses. Individual samples or entire batches may be repeated. Samples are batched together per confirmation method, which often contain multiple drug classes. When a batch is run, one sample may need one drug class to be tested, while another sample is tested for a different drug class. The entire batch is repeated if the chromatography is poor, the internal standards are not resolved, if there is an instrument issue, or the quality control or calibration data is out for multiple compounds in a batch. When the data presents an issue for a single compound (e.g., morphine), while the data for all other compounds are acceptable, only the samples with problematic single compound are repeated and the results for other samples with acceptable data are released.

Repeat Testing #2 – Explain the process for repeat testing. The policy states that if a QC is not acceptable, no positive results may be released. It does not state that negative results are held for repeat testing.

When reviewing data, the certifier first determines is if the internal standards are present and recovery is acceptable. If the internal standard is not detectable for a given sample, that sample is always re-queued, re-prepped, and reanalyzed (see response to QC #1). When the internal standard is present, the extraction worked; therefore, samples may be determined to be negative for the drugs examined and the results released.

Per FDT.02080 – The Director (not designee) must review monthly QC. Submit evidence of monthly review of quality control results and maintenance/equipment records by the director (not designee) for December.

While I was the Laboratory Director, I always reviewed the quality control results weekly and maintenance/equipment logs at least monthly. These reviews were not conducted by a designee. The Laboratory Director Review form is used for both weekly quality control data review, as well as monthly equipment log reviews. On September 14, 2020, Sarah Riley joined Averhealth as the Laboratory Director and I assumed the role of Clinical Consultant. During this transition, I offered to perform the reviews for a few additional weeks to afford Sarah Riley time to transition into the Laboratory Director role. Sarah Riley agreed to begin performing all reviews in October; however, she did not complete this responsibility. The only lapse in the review logs by the Laboratory Director occurred during the brief five-week period from October 10, 2020 to November 3, 2020, while Sarah Riley was the Laboratory Director. During this time period Sarah Riley failed to complete her required duties. Upon Ms. Riley's abrupt and unexpected departure, I resumed the Laboratory Director role and have since retroactively completed the reviews for this five-week time period to bring all reviews current and continue to complete weekly and monthly reviews on a timely basis.

Attachments G1 to G3, provide the December review of quality control results and maintenance/equipment records for December to date.

Lab Director QC Review 7-26-19 to 8-15-20 for instrument "Venom" states Benzos out for OF; Instrument "Poison Ivy" values for hair are not accurate. Submit corrective action taken.

This statement refers to the log sheet data entry error. Quality control data is manually tracked. The data entry error was subsequently addressed when I corrected the out-of-place values. This correction was documented in the Laboratory Director review of 12-4-20, Attachment G1.

Laboratory states that "Retest Results Variances" are expected to differ by +/-20%. FDT.02030 applies to criteria for acceptance/rejection of quantitative QC results and not patient samples. Provide supportive evidence for this statement.

This statement was part of a customer education piece that explains quantitative differences for a specimen tested twice with time lapse between tests.

It has been known for many years that drugs can degrade in storage. The extent of this degradation of various drugs in urine and oral fluid has been the subject of many studies (please see the below Sample Degradation References). Depending on the drug, the matrix and the storage conditions, drug loss can exceed 20% over 30 days. Proficiency testing results are deemed acceptable when results are within two standard deviations from the mean of all responses or

from the target value. In addition, analytical variance occurs when testing specimens through the exact same process and instrumentation. To put all of this in non-scientific terms for our customers' benefit, we translated that to +/- 20%.

Sample Degradation References

1. K.R. Allen, *Ann. Clin. Biochem*; 2011;48:531-541. DOI:10.1258/acb.2011.011116
2. K. Langel et al,. *J. Anal. Tox*; 2008;32: 1-9.
3. D. Lee et al., *Clinical Chem*;2012;58:7, 1101-1109.

Signed Acknowledgement Form

Attachment H, Signed Acknowledgement Form

As you can see based upon the records submitted, we have developed and adhere to polices that ensure compliance with CAP-FDT requirements. On a regular basis, Averhealth reviews SOPs and conducts ongoing staff training to ensure that SOPs are followed. As you review the information enclosed herein, please do not hesitate to reach out to me at mglinn@averhealth.com.

We look forward to resolving this matter as quickly as possible and appreciate your time and effort as you review all of the documentation.

Best,

Michele A. Glinn

Michele Glinn, PhD, F-ABFT
Laboratory Director

COLLEGE OF AMERICAN PATHOLOGISTS
CAP ACCREDITATION PROGRAMS

ACKNOWLEDGEMENT FORM

Suggestions for Responding to an Investigation:

- For complaint investigations provide a summary statement addressing all allegations.
- Provide supporting documentation as requested. Designate key information on documents, and avoid submitting excess pages when possible.
- Clearly label all supporting documentation by referencing allegation numbers, CMS D tags, other agency citations, CAP checklist requirements, or other attachment designations.
- To facilitate document imaging avoid the use of staples, page protectors, or binders, and submit single-sided documents.
- Responses may be sent by mail or commercial carrier. Email may be used if file sizes are less than 25 MB.

Acknowledgement Statement:

I attest that the laboratory's (Avertest LLC d/b/a Averhealth Laboratory, CAP # 8729023) responses and supplemental documentation for the College of American Pathologists have been reviewed and, to my knowledge, are complete and accurate.

Michele Glinn, PhD, Laboratory Director

Michele A Glinn 12-31-20

(signature and date)

Please complete this form and return it with your response to this investigation to:

Investigations Department
CAP Accreditation Programs
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750

AU ID # 1690070
Reference # 10219

CXADLDOC

Attachment A1, UDC LIFs

cap PT Exception Investigation Checklist

Survey Information

Survey Name: UDC A 2019 CAP No. 8729023

Date Survey Received: 1/8/19 Date Analysis Performed: 2/14/19 to 2/22/19

Date Survey Results Submitted: Date Results Received:

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 2/15/19

Unacceptable Result 1

Specimen Number: UDC-06 Analyte: Hydrocodone

Reported Result: 344 Intended Result/Range: 507

Unacceptable Result 2

Specimen Number: UDC-08 Analyte: MDA

Reported Result: 960 Intended Result/Range: 648

Unacceptable Result 3

Specimen Number: UDC-10 Analyte: 6MAM

Reported Result: 11.7 Intended Result/Range: 8.4

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf. Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: Repeat analysis: 6MAM 8.8, acceptable; Hydrocodone 479, acceptable; MDA same as previous. Original calibrators put on-line 1-16-19, two days before UDC-A samples received.

OFD-D 2018 results also showed MDA results elevated. This indicates not a problem with calibrators. MDA generally uses Amp-D5 as IS. Use of Amp-D5 or Methamp-D5 results in higher than expected results. Use of 6-MAM-D3 IS results in acceptable results for both original and repeat values (663 ng/mL).

Staff training on 3-6-19 includes using 6-MAM-D3 as IS for MDA and MDMA.

Corrective action documentation:

Review/approval: Michelle Gu

Date: 2-15-19

cap PT Exception Investigation Checklist

Survey Information

Survey Name: UDC-B 2019 CAP No. 8729023

Date Survey Received: 4/20/19 Date Analysis Performed: 5/1/19

Date Survey Results Submitted: Date Results Received: 6/3/19

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 6/5/19

Unacceptable Result 1

Specimen Number: UDC11 to UDC-20 Analyte: Creatinine

Reported Result: 49.1 to 60.8 Intended Result/Range: 63.46 to 81.79

Unacceptable Result 2

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 3

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result Intended Result/Range.

Unacceptable Result 5

Specimen Number Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

1728

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf. Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition* CLSI document GP27-A2. 2007.

Conclusion/Summary: Repeat analysis were acceptable for creatinine. Unclear why low initially. Laboratory switching to Microgenics reagent as soon as validation is complete.

Corrective action documentation:

Review/approval: 6.5.19

Date: _____

cap PT Exception Investigation Checklist

Survey Information

Survey Name: UDC-C 2019 CAP No. 8729023

Date Survey Received: 8/219 Date Analysis Performed: 9/12/19

Date Survey Results Submitted: Date Results Received: 9/4/19

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 9/19/19

Unacceptable Result 1

Specimen Number: UDC-24 Analyte: PCP

Reported Result: 109 - 186 Intended Result/Range: 244

Unacceptable Result 2

Specimen Number: UDC-25 Analyte: EDDP

Reported Result: 427-689 Intended Result/Range: 698

Unacceptable Result 3

Specimen Number: UDC 28 Analyte: 6 MAM

Reported Result: 22 Intended Result/Range: 11 - 21

Unacceptable Result 4

Specimen Number: UDC 29 Analyte: THCCOOH

Reported Result: 13 Intended Result/Range: 4 - 12

Unacceptable Result 5

Specimen Number: UDC 23 Analyte: pH

Reported Result: 12.7 Intended Result/Range: 9.5-11.9

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

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Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf. Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: All acceptable upon repeat.

Corrective action documentation:

Review/approval: M. Glinn

Date: 9-19-19

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cap PT Exception Investigation Checklist

Survey Information

Survey Name: UDC-D 2019 CAP No. 8729023

Date Survey Received: 11/5/19 Date Analysis Performed: 12/5/19

Date Survey Results Submitted: Date Results Received:

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 12/5/19

Unacceptable Result 1

Specimen Number: UDC-33 Analyte: Creatinine

Reported Result: 6.6 Intended Result/Range: < 2

Unacceptable Result 2

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 3

Specimen Number: Analyte:

Reported Result: Intended Result/Range.

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

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Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: Repeat analysis obtained 0.6 mg/dL; acceptable.

Corrective action documentation:

Review/approval: Michele A Gu

Date: 12.5.19

cap PT Exception Investigation Checklist

Survey Information

Survey Name: UDC A 2020 CAP No. 8729023

Date Survey Received: 1/8/20 Date Analysis Performed:

Date Survey Results Submitted: Date Results Received: 2/10/20

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 2/12/20

Unacceptable Result 1

Specimen Number: UDA 01 Analyte: MDMA

Reported Result: 1859 Intended Result/Range: 4736 +/- 715

Unacceptable Result 2

Specimen Number: UDC 06 Analyte: Oxycodone

Reported Result: 4800 Intended Result/Range: 2103 +/- 294

Unacceptable Result 3

Specimen Number: UDC-10 Analyte: Benzoylecgonine

Reported Result: 43 Intended Result/Range 73 +/- 9

Unacceptable Result 4

Specimen Number: UDC 02 and UDC 07 Analyte: pH

Reported Result: 6.1, 5.8 Intended Result/Range: 6.7, 6.5

Unacceptable Result 5

Specimen Number: UDC 01, 05, 06, 09 Analyte: SG

Reported Result: 1.004, 1.005, 1.005, 1.006 Intended Result/Range: 1.017 (all)

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http //www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf . Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: SG and pH originally analyzed with Axiom Test True. Repeat analyses done with Microgrenics, all acceptable Quantitative analysis of MDMA, oxycodone and benzoylecgonine repeated with new calibrators; all acceptable.

Corrective action documentation: Attached

Review/approval: Michele Glinn

Date: 2-12-20

cap PT Exception Investigation Checklist

Survey Information

Survey Name: UDC-B 2020 CAP No. 8729023

Date Survey Received: 4/28/20 Date Analysis Performed:

Date Survey Results Submitted: Date Results Received: July 2020

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 7/12/20

Unacceptable Result 1

Specimen Number: UDC-11 Analyte Hydromorphone

Reported Result: 388 Intended Result/Range: 229 - 358

Unacceptable Result 2

Specimen Number: UDC-12 Analyte: PCP

Reported Result: 63 Intended Result/Range. 38 - 58

Unacceptable Result 3

Specimen Number: UDC-15 Analyte: Temazepam

Reported Result: 912 Intended Result/Range. 556-871

Unacceptable Result 4

Specimen Number: UDC-17 Analyte pH

Reported Result: 6 2 Intended Result/Range: 6.28 - 7.11

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result. Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

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Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

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Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: Repeat analysis for pH, PCP, hydromorphone and temazepam were all acceptable. Same compounds as were problematic in the OFD-B scheme. Calibration schemes and quantitation methods checked for accuracy by Christina Essington. Reference material checked to be sure it was correct compound and concentration. D5-temazepam was ordered as a new internal standard and will be assessed to see if it gives more reliable quantitative results Results will be reported after assessment.

Corrective action documentation:

Review/approval: Michael A Gu

Date: 7-12-20

cap PT Exception Investigation Checklist

Survey Information

Survey Name: UDC-D 2020 CAP No. 8729023

Date Survey Received: 11/24/20 Date Analysis Performed. 12/16/20

Date Survey Results Submitted: Date Results Received: 12/4/20

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 12/20/20

Unacceptable Result 1

Specimen Number. UDC 35, 39 Analyte: THC-COOH

Reported Result· 166. 17 Intended Result/Range. 80, 9 (app. 50%)

Unacceptable Result 2

Specimen Number: UDC 36, 38 Analyte. MDMA

Reported Result· 2000, 1198 Intended Result/Range: 2757, 2734

Unacceptable Result 3

Specimen Number: OFD 36 Analyte: MDA

Reported Result· 737 Intended Result/Range: 1280

Unacceptable Result 4

Specimen Number: UDC 40 Analyte: 6MAM

Reported Result 22 Intended Result/Range: 40

Unacceptable Result 5

Specimen Number: 32, 34,, 36, 38, 39, 40 Analyte: pH

Reported Result· 6.1 - 6.3 Intended Result/Range: 6.4 - 7.1

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

1728

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

1728

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf. Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: General issues of poor chromatography this PT. Repeats showed all acceptable except 6-MAM, which is still high. OFD-D also had 6-MAM reported too high. Will evaluate standard reference material for possible evaporation/concentration.

pH repeats are acceptable on one instrument, but still too low on another, even after recalibrating. Re-ran all UDC-D samples on all five instruments. All would have been in the acceptable range except Starfire, which is consistently a pH unit lower than that others (see attached chart). Taking pH off Starfire until resolved. Support has confirmed that no pH values were flagged as abnormally low in the last six months, and that only one sample had a pH level above 10, and it was run on Robin. Checking with MLS about potential hardware issue.

Corrective action documentation:

Review/approval: Michael G

Date: 12-20-20

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Creat

UDC-D	31	32	33	34	35	36	37	38
Robin	72.5	88.6	1.9	84	91.6	91.6	91.3	93.5
Joker	73.5	92.2	2.1	89.4	96.4	97.4	95.5	97.9
Vixen	74.6	93.2	2.2	89	97.3	98.9	98.3	99.7
Hawkgirl	74.5	93.3	2	87	97.5	94.8	96.6	95.7
Starfire	72.5	90.5	2	86.2	94.1	94.8	93.4	96.3
R Diff From Mean	1.728228	4.008667	8.433735	4.43686	4.905269	5.053123	4.846274	4.004107

All acceptable per CAP UDC-D evaluation

pH

UDC-D	31	32	33	34	35	36	37	38
Robin	6.8	6.7	5.6	6.8	6.7	6.8	3.5	6.8
Joker	6.4	6.4	5	6.5	6.5	6.5	3.4	6.5
Vixen	6.7	6.7	5.3	6.8	6.8	6.7	3.6	6.8
Hawkgirl	6.4	6.4	5.1	6.4	6.5	6.5	3.6	6.5
Starfire	5.7	5.8	4.8	5.8	5.9	5.9	3.4	5.9

39	40
73.1	91.6
75	95
76.2	95.1
74.8	94.6
74.1	94.1
2.565811	3.273495

39	40
6.8	6.8
6.5	6.5
6.8	6.8
6.5	6.6
5.9	5.9

Attachment A2, OFD LIFs

cap PT Exception Investigation Checklist

Survey Information

Survey Name. OFD-C 2019 CAP No. 8729023

Date Survey Received: 9/5/19 Date Analysis Performed: 10/9/19

Date Survey Results Submitted: Date Results Received: 10/8/19

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date 10/9/19

Unacceptable Result 1

Specimen Number: OFD-15 Analyte: Amp Grp

Reported Result: Neg Intended Result/Range: Pos

Unacceptable Result 2

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 3

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

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Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf. Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: Repeat analysis was the same. Amp screened just under cutoff. 30 ng/mL amphetamine in the oral fluid sample is 10 ng/mL in the Quantisal container, so this is a correct result. 18 of 22 labs reported amphetamine as Absent. The Qual section of the evaluation (page 9) calls it Note 26 so this appears to be CAP's error.

Corrective action documentation:

Review/approval: Michael A-OL

Date: 10-9-19

cap PT Exception Investigation Checklist

Survey Information

Survey Name: OFD-D 2019 CAP No. 8729023

Date Survey Received: 12/3/19 Date Analysis Performed: 1/10/20

Date Survey Results Submitted: Date Results Received:

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 1/20/19

Unacceptable Result 1

Specimen Number: OFD-19 Analyte: Benzoylecgonine

Reported Result: 366 Intended Result/Range: 201

Unacceptable Result 2

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 3

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf . Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: Reanalyzing with new calibrators gave acceptable results (221 ng/mL).

Corrective action documentation:

Review/approval: Michele A. G

Date: 1-20-20

cap PT Exception Investigation Checklist

Survey Information

Survey Name: OFD-A 2020 CAP No. 8729023

Date Survey Received: 3/3/20 Date Analysis Performed: 4/14/20

Date Survey Results Submitted: Date Results Received: 4/13/20

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 4/15/20

Unacceptable Result 1

Specimen Number: OFD-02 Analyte: Nordiazepam

Reported Result: 11 Intended Result/Range: 14 - 85

Unacceptable Result 2

Specimen Number: OFD-05 Analyte: Methadone Grp

Reported Result: Neg Intended Result/Range: Pos

Unacceptable Result 3

Specimen Number: Analyte:

Reported Result Intended Result/Range:

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: OFD-02: Repeat quantitative analysis was acceptable for Nordiazepam (similar for other drugs in sample). Different internal standard now in use for Nordiazepam as it has been found to give more consistent results. Methadone qualitative was just below cutoff, reported negative per laboratory policy.

Corrective action documentation:

Review/approval: 4/15/20

Date: Michele Glinn

cap PT Exception Investigation Checklist

Survey Information

Survey Name: OFD-B 2020 CAP No. 8729023

Date Survey Received: 5/27/20 Date Analysis Performed:

Date Survey Results Submitted: Date Results Received: July 2020

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 7/12/20

Unacceptable Result 1

Specimen Number: OFD-06 Analyte: Hydromorphone

Reported Result: 99.97 Intended Result/Range: 51-99

Unacceptable Result 2

Specimen Number: OFD-08 Analyte: PCP

Reported Result: 35.98 Intended Result/Range: 16.7-33.4

Unacceptable Result 3

Specimen Number: OFD-09 Analyte: Temazepam

Reported Result: 77.03 Intended Result/Range: 22-55

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as Indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

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Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: Repeat analysis for PCP (Spl) and hydromorphone (Ml OF) acceptable. Temazepam extremely variable (see result summary spreadsheet). Ml OF and Abbr both gave high and then low results. Unclear if compound is not stable and degraded in the tube. Calibration scheme and quantitation methods checked for accuracy by Christina Essington. Reference material checked to be sure it was correct compound and concentration. D5-temazepam was ordered as a new internal standard and will be assessed to see if it gives more reliable quantitative results. Results will be reported after assessment.

Corrective action documentation:

Review/approval: Michael O

Date: 7-12-20

cap PT Exception Investigation Checklist

Survey Information

Survey Name: OFD-C 2020 CAP No. 8729023

Date Survey Received: 9/1/20 Date Analysis Performed: 9/2/20

Date Survey Results Submitted: Date Results Received: 10/8/19

Investigation Performed By: Michele Glinn

Lab Director: Michele Glinn Date: 10/9/20

Unacceptable Result 1

Specimen Number: OFD-12 Analyte: PCP

Reported Result: Neg Intended Result/Range: Positive - 5.9 - 14.3 ng/mL

Unacceptable Result 2

Specimen Number: OFD-13 Analyte: Methadone

Reported Result: 117 Intended Result/Range: 15.2 - 102

Unacceptable Result 3

Specimen Number: OFD-14 Analyte: Methamphetamine

Reported Result: 119 Intended Result/Range 50 - 106

Unacceptable Result 4

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Unacceptable Result 5

Specimen Number: Analyte:

Reported Result: Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☒	☐	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf. Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition.* CLSI document GP27-A2. 2007.

Conclusion/Summary: Methadone acceptable upon repeat. Methamphetamine analyzed initially by both MI OF and Standard panel calibration curves - the latter twice. Much variability between the three results; MI results reports as the first obtained and the more extensive curve. However, either of the Standard Panel results would have been acceptable. Calibration scheme of the two assays is being harmonized. PCP was clearly present at ~ 2 ng/mL by LCMSMS (calibration, QCs, chromatography all acceptable). This is consistent with the immunoassay screen result of ~ 2.7 ng/mL, which was repeated and obtained again. This result would not have been reported under our current policies. 18 of 98 labs also reported negative, so there may have been an issue with the composition of this sample.

Corrective action documentation:

Review/approval: 10-9-20

Date: Michele A. G

Attachment A3, LN6-B LIF

PT Exception Investigation Checklist

Survey Information

Survey Name: LN6-B
CAP No. 8729023
Date Survey Received: 11/17/20
Date Analysis Performed: 11/18/20 to 11/23/20
Date Survey Results Submitted:
Date Results Received: 12/18/20
Investigation Performed By: Michele Glinn
Lab Director: Michele Glinn
Date: 12/23/20

Unacceptable Result 1

Specimen Number: LN19-24
Analyte: Creatinine
Reported Result: 19 - 358
Intended Result/Range: 14 - 393

Unacceptable Result 2

Specimen Number:
Analyte:
Reported Result:
Intended Result/Range.

Unacceptable Result 3

Specimen Number:
Analyte.
Reported Result:
Intended Result/Range:

Unacceptable Result 4

Specimen Number
Analyte.
Reported Result:
Intended Result/Range:

Unacceptable Result 5

Specimen Number:
Analyte:
Reported Result:
Intended Result/Range:

Evaluation of Possible Sources of Error

Clerical	YES	NO	N/A
Was the result correctly transcribed from the instrument read-out or report?	☒	☐	☐
Was the correct instrument/method/reagent reported on the result form?	☒	☐	☐
Do the units of measure match between the result form and the instrument results?	☒	☐	☐
Is the decimal place correct?	☒	☐	☐
Does the result reported on the result form match the result found on the proficiency testing evaluation report?	☒	☐	☐

A response of "No" to any of these questions may indicate a clerical error Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

Procedural	YES	NO	N/A
Was the written procedure followed?	☒	☐	☐
Were the reagents prepared according to procedure?	☒	☐	☐
Were the reagents within their open stability acceptable range?	☐	☒	☐
Were Quality Control results acceptable and without bias?	☒	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☒
Was culture media stored per manufacturer's instructions?	☐	☐	☒
Was staining performed and interpreted correctly?	☐	☐	☒
Were dilutions performed correctly?	☒	☐	☐
Were calculations performed correctly?	☒	☐	☐

A response of "No" to any of these questions may indicate a procedural error These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	YES	NO	N/A
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?	☒	☐	☐
Does a review of the past proficiency testing results indicate evenly distributed data without bias?	☒	☐	☐
Was the intended result within the measuring range for the instrument?	☒	☐	☐
Was instrument maintenance performed on schedule?	☒	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?	☒	☐	☐

A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling	YES	NO	N/A
Were Survey specimens reconstituted as indicated in the Kit Instructions?	☒	☐	☐
Were Survey specimens stored as indicated in the Kit Instructions?	☒	☐	☐
Were any special instructions provided in the Kit Instructions performed as indicated?	☒	☐	☐
Were the correct tests performed on the correct vial of proficiency testing material?	☒	☐	☐

A response of "No" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials

PT Material	YES	NO	N/A
Was proficiency testing material received in the laboratory within an appropriate time after shipment?	☒	☐	☐
Were proficiency testing materials received at the appropriate temperature?	☒	☐	☐
Were stability limits exceeded?	☒	☐	☐
Were your results graded in the appropriate peer group based on the method reported on the result form?	☒	☐	☐

A response of "No" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer

Troubleshooting Guide for Proficiency Testing Data Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf Accessed January 26, 2011

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition* CLSI document GP27-A2. 2007.

Conclusion/Summary: Original results (run A, 11/17/20) acceptable Run B done the next day; results were higher. The variance between the two was outside the limit of acceptability. Repeated twice more on 11/23/20, same instrument, results were closer to each other but higher than previous. Appears that every time the samples were run, the results were higher. Original run (run A) would have been acceptable and comparable to results previously reported Kit instructions say to run within 1 hour of reaching room temperature and samples are stable for 5 days unopened at 2 - 8 degrees.

UDC-D samples were run on all instruments to compare creatinine results to ensure no bias. These were all acceptable

Root cause appears to be not running the original samples twice within window of stability. Going forward we will ensure all samples are run twice on the same day within an hour of being opened so as to avoid this issue.

Corrective action documentation: Repeats for LN6-B and UDC-D creatinine samples, kit instructions

Review/approval: Michele A Glen

Date: 12-23-20

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 - http //www cap org
Advancing Excellence

CAP Number: 8729023-02 **Kit #:** 01
Institution: Avertest LLC d/b/a averhealth Averh
Attention: Michele Glinn PhD
City/State: Saint Louis, MO 63134-3142

Kit ID: 32828716
Kit Mailed: 11/16/2020
Original Evaluation: 12/18/2020
Next Mailing Date: 03/22/2021

EVALUATION
ORIGINAL

LN6-B 2020 Urine Chemistry Calibration Verification/Linearity

Executive Summary

Analyte	Calibration Verification	Linearity Evaluation	Page #
Creatinine mg/dL	***Different***	* Linear from 19.150 to 347.250	2 - 3

Note: For results of Different, see the Calibration Verification Troubleshooting Guide and Investigation Checklist.

* This range does not include all reported specimens Review your results to determine if excluded specimens reveal possible analytical problems

Reviewed by_____ Date_____

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 - http //www cap org
Advancing Excellence

CAP Number: 8729023-02 **Kit #:** 01
Institution: Avertest LLC d/b/a averhealth Averh
Attention: Michele Glinn PhD
City/State: Saint Louis, MO 63134-3142

Kit ID: 32828716
Kit Mailed: 11/16/2020
Original Evaluation: 12/18/2020
Next Mailing Date: 03/22/2021

EVALUATION
ORIGINAL

LN6-B 2020 Urine Chemistry Calibration Verification/Linearity
Creatinine mg/dL Calibration Verification Evaluation

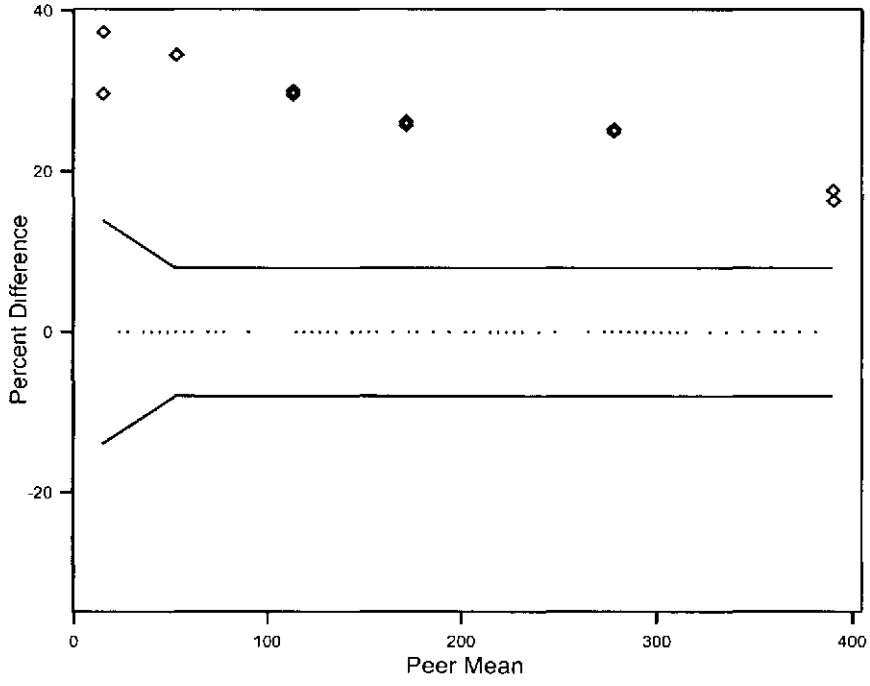
Evaluation Result: Different

Peer Instrument· BECKMAN AU SERIES
Peer Method KINETIC ALK PICRATE

Allowable Error· 8% or 2 mg/dL, whichever is greater

Specimen	Assay 1	Assay 2	Your Mean	Peer Mean	Peer N	Difference	Allowable Error
LN6-19	18 60	19 70	19 150	14 336	125	4.814 mg/dL	± 2 000 mg/dL
LN6-20	70.40	70.30	70 350	52 284	125	34 6%	± 8.0%
LN6-21	146 20	146 70	146 450	112 779	125	29 9%	± 8 0%
LN6-22	215.30	216 10	215 700	171.162	125	26 0%	± 8 0%
LN6-23	346 80	347 70	347 250	277 550	124	25 1%	± 8 0%
LN6-24	453 50	458.70	456.100	389.723	116	17.0%	± 8.0%

Calibration Verification Plot Percent Differences with Allowable Error Limits



Peer Results Summary Table

Peer Group Size 125

Range	Calibration Verification		Linearity Evaluation		
	% Verified	% Different	% Linear	% Nonlinear	% Imprecise
LN6-19 - 24	65.6	19.2	84 0	0 0	0.0
LN6-19 - 23	13.6	0.0	15.2	0.0	0.0
LN6-19 - 22	0.8	0.8	0.8	0.0	0.0

College of American Pathologists
325 Waukegan Road, Northfield Illinois 60093-2750
800-323-4040 - http //www cap org

Advancing Excellence

CAP Number: 8729023-02 **Kit #:** 01
Institution: Avertest LLC d/b/a averhealth Averh
Attention: Michele Glinn PhD
City/State: Saint Louis, MO 63134-3142

Kit ID: 32828716
Kit Mailed: 11/16/2020
Original Evaluation: 12/18/2020
Next Mailing Date: 03/22/2021

EVALUATION
ORIGINAL

LN6-B 2020 Urine Chemistry Calibration Verification/Linearity
Creatinine mg/dL Linearity Evaluation

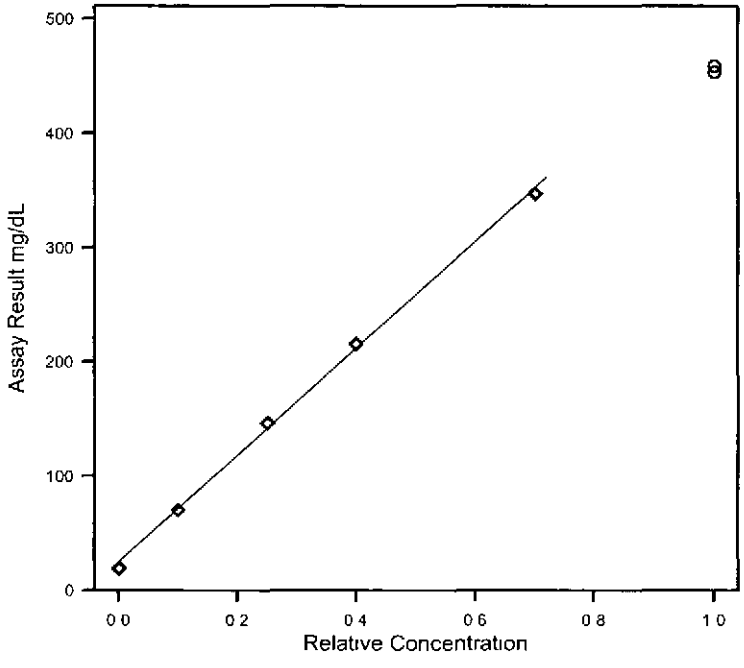
Evaluation Result: Linear from 19.150 to 347.250

Instrument. BECKMAN AU SERIES
Method· KINETIC ALK PICRATE

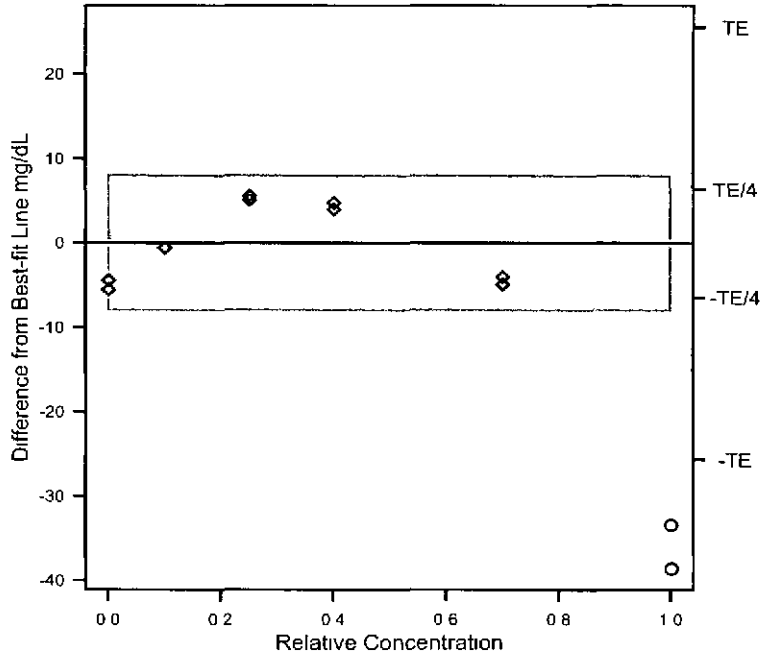
Evaluation Type Standard
Goal for Total Error (TE) 16%
Mean of Included Results 159 780 mg/dL

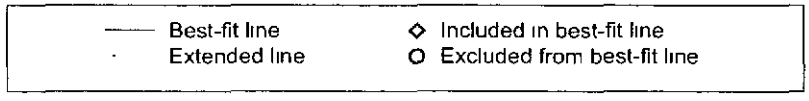
Specimen	Assay 1	Assay 2	Your Mean	Best-fit Target	Relative Concentration
LN6-19	18.60	19.70	19 150	24.074	0.000
LN6-20	70.40	70 30	70 350	70 869	0 100
LN6-21	146 20	146 70	146 450	141.062	0.250
LN6-22	215 30	216 10	215 700	211 255	0 400
LN6-23	346 80	347 70	347.250	351.640	0 700
LN6-24	453 50	458 70	456.100	492 026	1 000

Linearity Plot 1· Reported Results with Best-fit Line



Linearity Plot 2· Differences with Limits of Acceptable Imprecision





Creat

UDC-D	31	32	33	34	35	36	37	38	39	40
Robin	72.5	88.6	1.9	84	91.6	91.6	91.3	93.5	73.1	91.6
Joker	73.5	92.2	2.1	89.4	96.4	97.4	95.5	97.9	75	95
Vixen	74.6	93.2	2.2	89	97.3	98.9	98.3	99.7	76.2	95.1
Hawkgirl	74.5	93.3	2	87	97.5	94.8	96.6	95.7	74.8	94.6
Starfire	72.5	90.5	2	86.2	94.1	94.8	93.4	96.3	74.1	94.1
R Diff From Mean	1.728228	4.008667	8.433735	4.43686	4.905269	5.053123	4.846274	4.004107	2.565811	3.273495

All acceptable per CAP UDC-D evaluation (looks like they gave 3 SDI on this measure)

pH

UDC-D	31	32	33	34	35	36	37	38	39	40
Robin	6.8	6.7	5.6	6.8	6.7	6.8	3.5	6.8	6.8	6.8
Joker	6.4	6.4	5	6.5	6.5	6.5	3.4	6.5	6.5	6.5
Vixen	6.7	6.7	5.3	6.8	6.8	6.7	3.6	6.8	6.8	6.8
Hawkgirl	6.4	6.4	5.1	6.4	6.5	6.5	3.6	6.5	6.5	6.6
Starfire	5.7	5.8	4.8	5.8	5.9	5.9	3.4	5.9	5.9	5.9

12/23/2020

Attachment B1, Quality Management Policy

averhealth

QUALITY MANAGEMENT

Written/Revised: *Michele Glinn | Laboratory Director*_____

Revision: *004 April 1, 2018*

Reviewed & Approved By:

*Dominique Delagnes | Chief Operating Officer*_____

Contents

Quality Management

Policy

Averhealth shall have a Quality Management (QM) program composed of quality assessment/quality control (QA/QC) procedures The program is intended to improve customer service by ensuring that specimens are completely accounted for throughout the testing process, are properly handled, tested and stored, that the correct tests are performed, that instruments and equipment used are in good working condition, that reagents and chemicals are of acceptable quality, that testing personnel are adequately trained, that results are accurate, that reported data is free from technical and administrative errors, that procedures for reporting errors are established, and that any errors or inconsistencies detected are corrected as quickly as practical The Laboratory Director and technical personnel are responsible for the ongoing systematic quality assessment monitoring system for evaluation of quality and appropriateness of services provided by the Laboratory staff All staff shall review and be familiar with the quality control requirements

The Quality Management Program will encompass all phases of Laboratory operation

- General
- Pre-Analytic
- Analytic
- Post-Analytic

Quality Management Procedures

Visitor and Employee Safety

The Laboratory will maintain a safe environment for visitors and employees Standard (Universal) precautions are observed, annual safety training is provided, and regular hazard surveys are conducted Incidents involving accidental injury or chemical or biohazard exposure will be investigated and the root cause addressed

Patient Confidentiality

The Laboratory will maintain the privacy of patient information throughout all phases of the testing process that is under its control Specimens are run in the Laboratory with a system driven accession number No name or identifier other than the accession number is printed on documentation throughout testing Compliance issues will be reviewed and addressed on a regular basis by designated personnel

Complaints and Communication Breakdowns

The Laboratory will ensure that all reported complaints and problems are documented The Laboratory will investigate all complaints and take appropriate action The Laboratory will use secure and appropriate communication channels for ordering tests, communicating with the patient service centers and customers, and reporting results The Laboratory will identify and document problems that occur as a result of communication breakdowns between the Laboratory and patient service centers or healthcare providers

Customer Satisfaction

The Laboratory surveys customer satisfaction by using a ticketing system through Microsoft Teamwork Desk This ticketing system allows the Laboratory to assign questions and support requests to various individuals at the Laboratory Customers may also provide feedback regarding the service received The Laboratory Director and administrative team monitor response times to ensure customers are receiving responses in a timely fashion

Personnel

The Laboratory hires qualified individuals and provide adequate training in job functions and responsibilities The Laboratory encourages continuing education and provide opportunities as appropriate The Laboratory establishes and follows written policies and procedures, as described in the CAP personnel requirements, to evaluate employee competency after initial training and annually thereafter

Vendor and Reference Lab Relationships

The Laboratory evaluates the service the Laboratory receives from vendors and reference labs and address any problems Any tests that the Laboratory sends out to a reference Laboratory will only be referred to a CAP-certified laboratory If an assay cannot be performed in-house, an aliquot of the specimen may be sent to a reference laboratory for analysis The collection site may order an external test through Aversys The order will appear in the External Lab queue Accessioners will send an aliquot with the appropriate requisition or chain of custody forms to the laboratory selected The results will be reviewed by the Laboratory Director or Designee, and the customer will be notified on the report that the analysis was performed by a third party

If any device or equipment recalls occur the Laboratory will take action to report use of device to the appropriate parties and to communicate with the vendor to resolve any issues resulting from use of the device Reports will be completed throughout the entire communication process and follow up will occur until the situation is resolved

Adverse Patient Event Reporting

When information reasonably suggests that any Laboratory instrument, reagent or other device has or may have caused or contributed to a patient death or serious patient injury, it is this Laboratory's policy to report the event If the event is death, the report must be made both to the FDA and the device manufacturer If the event is serious patient injury, the report may be to the manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to the FDA. Reports must be submitted on the FDA Form 3500A (or an electronic equivalent) as soon as practical as but no later than 10 days from the time medical personnel become aware of the event

The FDA defines "serious patient injury" as one that is life threatening, or results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, labeling, reagents or calibration, or to user error (since the latter may be related to faulty instrument instructions or design) An adverse patient event that may have resulted from inherent limitations in an analytic system (e g limitations of sensitivity, specificity, accuracy, and precision) is not reportable

The Laboratory submits an annual report of device-related deaths and serious injuries to FDA, if any such event was reported during the previous year Annual reports must be submitted on Form 3500 by January 1 of each year The Laboratory or institution must keep records of MDR reports for 2 years

Federal/State/Local Regulations

The Laboratory follows all regulations and laws for any federal, state, or local entity whose jurisdiction our certificates, location, or customer needs fall under

Interim Self-Inspection

For each year the facility goes without a formal inspection, an interim in-house inspection will be performed according to CAP inspection criteria Any issues identified will be documented and resolved as soon as practical

Terms of Accreditation

This Laboratory will follow and remain complaint with all CAP terms of accreditation including the following

- Investigation of the Laboratory by a government entity or other oversight agency, or adverse media attention related to Laboratory performance, notification must occur no later than two working days after the Laboratory learns of an investigation or adverse media attention For laboratories subject to US regulations, this notification must include any complaint investigations

conducted or warning letters issued by any oversight agency (e g CMS, State Department of Health, The Joint Commission, FDA, OSHA).

- A facility must notify the College of American Pathologists as soon as it finds itself to be the subject of a validation inspection
- Discovery of actions by Laboratory personnel that violate national, state or local regulations
- Change in Laboratory test menu prior to beginning that testing or the Laboratory permanently or temporarily discontinues some or all testing
- Change in Laboratory Directorship, location, ownership, name, insolvency, or bankruptcy, notification must occur no later than 30 days prior to the change(s), or, in the case of unexpected changes, no later than two working days afterwards Laboratories subject to US regulations must also notify the US Department of Health and Human Services
- Provision of a trained inspection team comparable in size and scope if requested by CAP at least once every two-year accreditation period
- Cooperation with CAP and HHS when the Laboratory is subject to a CAP or HHS complaint investigation or validation inspection
- Adherence to the Terms of Use for the CAP Certification Mark of accreditation
- For laboratories subject to US regulations, availability, on a reasonable basis of the Laboratory's annual proficiency testing results upon request of any person

Turnaround Time

The target turnaround times are as follows

- Negative screened specimens are reported by end of next operating day following receipt at the Laboratory
- Positive screened specimens are reported within 72 hours from the start of confirmation testing
- If the Laboratory is notified that a customer needs expedited results, every effort will be made to have the specimen analyzed in the next available batch to accommodate the customer's timetable
- Extenuating circumstances that could cause delays in reporting are relayed to the patient service centers so that they may communicate to customers

Pre-Analytic Phase

Test Ordering

Averhealth requires written or electronic authorization for patient testing from an authorized provider or customer Tests are generally ordered at the collection site Test requests must contain essential information that identifies the ordering provider or customer, including contact information, patient identification, gender, age, date of birth, tests ordered, type of specimen, date and time of specimen collection, and any additional information necessary to ensure accurate and timely testing and reporting of results. All test orders and identifiers that are entered into the system are checked for accuracy

Specimen Collection, Labeling, and Handling

Averhealth has written policies for specimen collection, labeling, processing, storage, transport and rejection Specimens will be transported to the laboratory by commercial carrier or private courier in sealed containers which preserve specimen integrity Refer to the Collection Manual and Accessioning sections for specifics.

Corrections

If any corrections must be made to a specimen label or order, a communication is sent by Teams or email to the site or area manager Results will not be released until the correct information is received and entered If the correct information cannot be located or assured, the sample will be rejected

Specimen Rejection

Specimens may be rejected for the following reasons

- The sample cannot be properly identified
- The sample appears to be contaminated
- The sample appears to be adulterated or substituted
- The sample contains interferents or background such that the analyzer is not able to accurately determine the drug content
- The quantity is not sufficient for analysis
- The tamper seal is broken or the container is not intact
- The customer has requested the analysis be halted

Specimen rejection will be documented in Aversys and on Microsoft Teams

Analytic

Procedure Manual

The Laboratory has written instructions for all tests performed by the Laboratory New procedures are signed and dated when put in use, and discontinued procedures are dated and retained for two years The procedure manual is accessible to Laboratory staff, kept up-to-date, and annually reviewed and approved by the Laboratory Director

Test Systems, Instruments, Reagents, and Supplies

The Laboratory's instrumentation and analytical protocols are thoroughly validated and meet the scientific needs of the clients Manufacturer's specifications are followed in use, maintenance and storage of all instruments, test kits and reagents The Laboratory manages its inventory and purchasing to prevent shortages and waste Reagents are monitored for acceptable labeling (identity of substance, open or preparation dates, expiration dates), handling and storage

Verification of Performance Specifications

When the Laboratory introduces any new non-waived test methods, the manufacturer's stated claims for the performance specifications of accuracy, precision, reportable range, and reference range are verified using the before testing patient samples For modified methods or methods that are not FDA approved, the Laboratory will establish its own performance specifications (see Method Validation section below) and include validation of analytical sensitivity and analytical specificity The Laboratory will ensure that the test systems continue to meet the expected performance specifications and take corrective action if they do not

Calibration and Calibration Verification

The Laboratory performs calibration at defined intervals – either every analytical run (LC/MS/MS), or when new reagent lots are placed in use, or when major instrument repairs are done, or when instrument performance appears to be degrading (see individual analytical procedures for details) The Laboratory performs calibration verification for qualitative and quantitative assays at least annually In the case of calibration verification failure, a root cause analysis will be conducted and the assay will not be run until the issue is resolved

Analytical Measurement Range Verification

For quantitative assays, analytical measurement range is measured at least annually (see Analytical Measurement Range policy) In the case of AMR failure, a root cause analysis will be done, and the range adjusted if necessary

Maintenance and Function Checks

The Laboratory understands the importance of proper instrument maintenance for optimum performance and longevity The Laboratory will perform all maintenance and function checks following the manufacturer's directions and at the recommended frequencies. The Laboratory documents all maintenance and function checks and takes corrective action when necessary

Quality Control Data

Appropriate controls will be run for all screening and confirmation panels (see individual procedures for specific controls and acceptable ranges). For immunoassays, controls will generally consist of values below and above the cutoff Quantiative assays will consist of low, medium and high value controls that span the analytical measurement range Blind controls will be logged into the system and analyzed as patient samples These may consist of spiked samples, blank matrix or previously analyzed proficiency test or patient samples All control data will be reviewed by qualified personnel before results of patient sample analysis are released If results are outside the acceptable range, results will not be released until the cause is identified and acceptable results obtained Troubleshooting procedures include re-running a new aliquot of the control, re-running a new lot of the control, re-calibration of the instrument, and contacting a qualified service technician Quality control results will be tracked over time in logs or in Aversys The results will be reviewed at least monthly by the Laboratory Director or designee, and the review documented

Instrument Comparison

Instruments that run the same assays will be compared twice per year to ensure that performance is equivalent Comparability will be assessed by statistical evaluation of quality control data, analysis of proficiency test samples or other appropriate method Documentation of comparisons will be maintained If performance of any instrumentation appears anomalous, a root cause analysis will be performed and the cause of the anomaly addressed

Proficiency Testing

The laboratory participates in proficiency testing (PT) surveys provided by CAP and other providers or sources as appropriate. PT specimens will be integrated into the regular workflow in the same manner as patient samples The results will be reviewed and reported by the Laboratory Director All testing personnel will participate in at least one proficiency test over the course of a calendar year Performance on proficiency testing will be reviewed by the Laboratory Director Unacceptable results will be reviewed and a root cause investigation performed No proficiency test samples will be referred to an external laboratory. No communications with another laboratory about PT samples will be done while a survey is in progress

Documentation

The Laboratory maintains the following records in electronic or hardcopy form

- Patient specimen identifiers
- Test data
- Test reported results
- Quality control performance for each analytical day or assay
- Calibration records
- Corrective actions
- Proficiency testing records
- Inspection records
- Personnel records
- Equipment logs
- Reagent and standard inventory, preparation, verification and use logs

Corrective actions may be documented in a written or electronic log, or on the lab report if appropriate All documentation will be retained for at least two years

Post-Analytic

Test Reports

Test reports from the Laboratory are reviewed periodically for accuracy, completeness of required information and patient identifiers, and turnaround times

Specimen Retention after Testing

The Laboratory retains negative urine and oral fluid specimens after testing for five days and positive specimens frozen in their original containers for one year, maintaining their identity and integrity to allow for repeat testing and add-on tests Positive hair specimens will be retained in their original containers for up to one year at ambient temperature The Laboratory will return specimens to proper storage conditions as soon as possible after testing The Laboratory properly discards specimens that are no longer needed or no longer viable for testing

Specimen Collection & Transport Communications

In case of transport errors or issues, the Laboratory will communicate with the site and the area manager by Teams or email to resolve the problem Sites may also alert the Laboratory to potential issues with incoming samples by the same media

Reporting

If customer results cannot be reported due to an analytical issue, the testing personnel must notify the Laboratory Director or designee The Laboratory Director or designee will decide if the testing needs to be referred out to another Laboratory or if the testing can be delayed until the problem is resolved If the turnaround time will exceed the expected period, customers will be notified Any deviations from procedure will be documented on the laboratory report

If an error is identified after the results have been released, the Laboratory Director or Designee must be promptly notified, and the incident documented A corrected report must be promptly issued as soon as the problem is rectified, and the customer specimen is repeated Amended reports, including those amended multiple times, will contain notations as to what was amended Exact copies of the original and corrected report must be maintained in electronic or hard copy form for two years along with documentation of the problem and remedial action

Corrective Actions

Any procedural errors discovered by Laboratory personnel must be reported to a supervisor immediately Any reports of suspected errors that are received from customers will be reported to the Laboratory Director or designee immediately. All procedural and technical errors will be investigated, and the appropriate corrective action taken Corrective actions may include repeat analyses, issuance of corrected reports, re-training of personnel and/or revisions of policies, depending on the nature of the error All corrective actions shall be recorded on a Corrective Action form with supporting documentation attached

Any action that requires an amended report shall be documented, and all related documents will be retained for two years

Specimens received from the customer with incorrect or incomplete documentation are not considered errors by the Laboratory and shall be handled according to the procedure outlined in the Accessioning policy

Method and Instrument Validation

Method Validation

All new methods will be extensively validated before being put into general use Validation will include evaluation of specificity, sensitivity, cutoff (if qualitative), upper and lower limits of quantitation (if quantitative), linearity (if quantitative), intra-day and inter-day accuracy and precision (if quantitative), accuracy around the cutoff (if qualitative), interferences and matrix effects Standards, quality control samples, spiked blanks, previously analyzed proficiency test samples or previously analyzed patient

samples may be used in the validation process as applicable All validation data will be recorded in a report which will be reviewed by the Laboratory Director Acceptability criteria will be specified The method must exhibit acceptable performance for all parameters before being put into general use

Instrument Validation

New instrumentation which are of the same model or type as current instrumentation, and which will be running the same methods, will be validated by assessing intra-day and inter-day accuracy and precision using quality control samples, repeat analysis of at least ten previously analyzed patient or proficiency test samples to show repeatability, and analysis of at least ten blank matrix samples to demonstrate lack of interferences

New instruments which are of a different type, or which will be running a new assay, will be considered as part of a new method and validated according to the Method Validation section above

Consultations

Upon request, the Laboratory Director will provide written scientific opinions or interpretations to clients All such documents will be supported by published scientific research and analytical data which may be provided upon request

Management Reviews

Quality control performance data will be reviewed by the laboratory director at least monthly, and weekly whenever possible The review will be documented, and anomalies will be investigated

Standard and reagent preparation and verification, equipment and environmental logs will be reviewed at least monthly by the Laboratory Director or designee Anomalies will be addressed

A hazard survey will be performed at least monthly by the Laboratory Director, safety officer or designee. Documented hazards will be addressed

At least annually, the Laboratory Director and averhealth management team will review the General, Pre-Analytic, Analytic and Post-Analytic operations The team will evaluate the policies and procedures for effectiveness and confirm that they are being followed consistently by all staff Results of the review will be maintained on file

At least annually, the Laboratory Director or averhealth management team will review the laboratory report format to ensure that it still meets client needs

At least annually, the Laboratory Director or averhealth management team will review confidentiality procedures to determine that they are still effective

Quality Management Procedures

Averhealth's Quality Management program will use the following processes to ensure compliance with procedures and monitor all phases of the Laboratory's operation

Procedure	Documentation
General Laboratory Procedures	
Adoption of SOPs for specimen collection	Specimen Collections Policy
Adoption of SOPs for Laboratory operations	Standard Operating Procedures
Adoption of SOPs for health and safety issues	Safety Procedures, Personnel Training Records
Adoption of standards for employee conduct	Employee Guidebook Acknowledgement
Documented training of all testing personnel	Personnel files
Participation in CAP-approved proficiency testing	CAP Proficiency Records

At least quarterly staff meetings to discuss administrative or technical issues	Personnel Training Records
Maintenance of archived procedures and policies	File storage documentation & Revision Logs
Biennial accreditation inspections	CAP inspection and accreditation documentation
Self-inspections during non-accreditation years	Inspection results maintained on file
Turnaround Time Review	Daily, Monthly and Annual Laboratory Director Review
Customer Satisfaction	Teamwork Desk Ticket records
Pre-Analytic Phase	
Establishment of criteria for specimen acceptance	Specimen collections policy and accessioning policies
SOPs for specimen tracking and inventory	Specimen shipment and accessioning policies
Review of customer and Patient documentation for accuracy	Accessioning policy
Monitoring of orders and reports for clerical and technical accuracy	Accessioning policy, management reviews
LIMS data integration review	Laboratory reports, LIMS QA reports
Analytic Phase	
Validation of all new methods/instruments	Validation Reports
Documentation of instrument performance through acceptable calibration and quality control data	Daily QC reports, management reviews
Documentation of acceptable instrument and equipment repair and maintenance	Instrument Maintenance Logs
Documentation of acceptable reagent and chemical quality	Reagent package inserts, reagent acceptance log
Other Instrument Calibrations	Instrumentation Logs
Proficiency Testing Review	Proficiency Testing Binder(s)
Levy Jennings Review	Laboratory Director reviews
Post-Analytic Phase	
Periodic reviews of random case data for technical and clerical accuracy	Laboratory Director reviews
Establishment of procedures for reporting technical or administrative errors and documentation of corrective actions	Individual analytical procedures, corrective action records
Periodic reviews of quality control data	Monthly and Annual Review Reports
Annual review of technical policies and procedures	Policies & Procedure Revision logs
Annual review of employee performance	Employee competency assessment
Annual review of effectiveness of QM program	Annual management review
Solicitation of customer feedback	Teamwork Desk tickets
Annual review of report format	Annual management review
Monitoring of patient confidentiality	Compliance committee meetings or annual review

Version	Title	Date	Initials
1	Policies and Procedures	March 2013	
2	Policies and Procedures	Sept 2014	
3	CAP General Procedures	March 2016	
4	Quality Management	April 1 2019	

Attachment B2, Instrument Comparison Data

averhealth

INSTRUMENT COMPARISON
NOVEMBER 2020

Michele A. Glinn

Michele A. Glinn, PhD, F-ABFT

Laboratory Director

Date: Dec 2, 2020

Contents

Purpose

CLIA/COLA requirement QA 12R specifies that if performing the same test using different methods or instruments, the variance in the results produced by each method must be evaluated at least twice per year The performance of the 5400 Autoanalyzers HG, VX and SF, and the LC/MS/MS instruments SM, FL, AQ, FS, LX, BN, PI, RD, LS, DS and VN were compared by statistical analysis of control performance at multiple points for analytes tested on multiple instruments

Summary

All instruments passed for all assays tested

Five-Instrument Comparisons, AU5400

Five-instrument comparisons were done using HG, VX, SF, JK and RB to determine whether the methods are equivalent High and low control results for each panel for each instrument taken over 18 days in November from the most frequently used assays were compared Data points were obtained from the log sheet maintained on the laboratory server and updated daily by technical staff Assays are qualitative Performance was acceptable if (a) the difference between each pair of instruments was less than 2 SDI of the most variable instrument and (b) the lowest and highest values for each control were within the acceptable ranges

Evaluation All assays passed Instrument performance is acceptable and clinically equivalent

Notes: None of the lowest or highest values recorded were outside the acceptable ranges

Inst	Control	Benz	EtG	THC	Barb	MTDN	PCP	AMP 500	Coc 300	OPI 300	Oxy	Creat	Methamp	Bup	Fent
Vixen															
Avgs	High	289 17	707 59	24 01	288 32	390 16	32 49	721 76	371 10	402 52	166 38	7 87	752 45	7 06	2 98
Std	High	24 25	66 94	3 22	27 02	28 94	3 96	80 48	36 08	35 59	16 80	0 19	67 89	0 94	0 40
Avg	Low	164 87	407 94	8 72	158 03	249 82	17 30	359 03	227 33	246 87	85 85	1 63	412 87	3 72	1 08
Std	Low	10 55	43 33	2 42	13 84	15 92	1 97	39 98	21 79	21 76	6 34	0 11	30 08	0 69	0 22
Hawkgirl															
Avgs	High	296 36	718 96	24 98	297 90	396 64	32 17	737 63	375 83	398 46	173 03	7 90	807 38	7 61	3 07
Std	High	28 19	43 95	2 29	17 02	22 37	2 44	83 44	20 26	34 10	16 54	0 22	92 27	0 99	0 39
Avg	Low	164 95	424 92	10 59	157 95	249 06	17 69	372 81	226 13	247 38	88 49	1 64	423 60	4 06	1 10
Std	Low	7 61	34 87	2 19	9 14	12 21	1 44	21 05	14 86	24 45	4 29	0 12	24 00	0 51	0 25
Starfire															
Avgs	High	292 68	725 19	24 93	303 42	395 51	32 63	789 60	382 96	399 86	172 01	7 75	801 95	7 20	3 02
Std	High	51 64	56 90	2 79	20 64	25 09	2 85	98 15	28 04	32 03	13 32	0 33	67 70	0 77	0 41
Avg	Low	165 75	413 48	8 88	160 00	249 84	18 14	409 40	231 88	243 75	87 49	1 62	420 17	3 92	1 04
Std	Low	11 09	40 11	3 10	9 49	13 22	2 33	44 20	28 87	25 54	6 73	0 10	24 07	0 54	0 26
Joker															
Avgs	High	304 07	717 76	23 17	291 90	398 53	33 16	744 71	365 82	380 57	167 93	7 80	741 15	7 43	3 46
Std	High	27 83	62 61	1 75	21 15	20 80	2 74	67 87	23 94	22 86	12 25	0 19	70 77	0 69	0 48
Avg	Low	162 43	426 14	8 32	154 66	250 67	17 11	360 62	217 44	234 83	85 06	1 60	392 71	4 00	1 30
Std	Low	5 36	42 76	1 91	11 33	15 05	2 47	31 99	35 61	16 93	6 82	0 11	31 33	0 39	0 24
Robin															
Avgs	High	289 09	720 15	24 67	294 29	396 43	32 07	751 39	391 04	379 83	171 66	7 80	746 91	7 13	3 21
Std	High	28 62	51 84	3 57	21 41	14 77	2 07	77 26	22 09	30 56	13 43	0 13	58 00	0 81	0 56
Avg	Low	166 72	441 42	9 42	155 22	250 25	17 74	383 11	229 38	238 88	85 41	1 60	395 58	3 94	1 34
Std	Low	9 27	36 54	2 62	11 12	12 26	1 79	27 59	13 32	21 07	7 00	0 10	23 78	0 46	0 36
Difference: Highest - Lowest															
	High	14 99	17 60	1 80	15 10	8 37	1 09	67 84	25 23	21 95	6 65	0 10	60 47	0 55	0 48
	Low	4 29	33 48	2 27	5 34	1 61	1 04	50 36	14 45	12 55	3 08	0 04	30 89	0 34	0 29

Multiple Instrument Comparisons, LC/MS/MS

Comparisons were done for each LC/MS/MS assay that was run on two or more instruments Most assays were only run on one instrument so no comparison was necessary Standard and Oral Fluid batches, however, were run on two and six instruments each respectively Quality control results run on each instrument from August through November 2020, for representative analytes in each panel were compared Data points were obtained from the log sheet maintained on the laboratory server and updated by technical staff Assays are quantitative For oral fluids, performance on the Michigan Oral Fluid assay was used to assess performance as this assay has the most analytes and greatest dynamic range

Performance was acceptable if the difference between analytes on each pair of instruments, or between the highest and lowest values obtained on a range of instruments, was less than 2 SDI of the more variable instrument for at least two of the three controls

Evaluation All assays passed Instrument performance is equivalent

Standard. Instruments: Riddler, Flash

Sample Name	Component Name	RD Avg	RD SD	RD %CV	FL Avg	FL SD	FL%CV	Diff
QC High	Benzoylecgonine 1	7113.33	598.62	8.42	7193.00	565.12	7.86	79.68
QC High	Benzoylecgonine 1	7655.19	1476.40	19.29	7560.48	509.40	6.74	94.71
QC Low	Benzoylecgonine 1	75.95	16.14	21.25	76.07	12.62	16.58	0.13
QC Low	Benzoylecgonine 1	79.30	20.52	25.88	76.14	15.89	20.86	3.16
QC Mid	Benzoylecgonine 1	788.21	87.62	11.12	812.74	72.46	8.92	24.53
QC Mid	Benzoylecgonine 1	795.49	68.25	8.58	793.05	39.77	5.02	2.44
QC High	Morphine 1	7829.45	979.07	12.50	7505.59	673.59	8.97	323.86
QC High	Morphine 1	7703.27	898.72	11.67	7490.07	900.60	12.02	213.20
QC Low	Morphine 1	77.15	13.83	17.92	76.03	13.93	18.32	1.12
QC Low	Morphine 1	78.85	18.58	23.56	75.23	19.13	25.43	3.62
QC Mid	Morphine 1	761.66	68.95	9.05	812.35	83.65	10.30	50.69
QC Mid	Morphine 1	761.25	98.58	12.95	791.85	109.70	13.85	30.60

Oral Fluid. Instruments: Aquaman, Bane, Darkseid, Lois, Lex, Venom

Sample	Component Name	AQ Avg	AQ Std	BN Avg	BN Std	DS Avg	DS Std	LS Avg	LS Std	Lx Avg	LX Std	VN Avg	VN Std	Diff High-Low
QC High	Benzoylecgonine 1	30 38	5 55	32 75	6 39	31 55	6 17	32 60	7 36	33 07	6 63	32 28	6 88	2 22
QC High	Benzoylecgonine 1	31 51	6 76	32 75	5 91	31 12	6 22	31 78	7 89	33 10	6 82	32 72	8 08	1 63
QC Low	Benzoylecgonine 1	7 78	1 01	7 85	0 98	7 81	0 96	7 83	1 38	8 05	1 39	7 82	1 13	0 27
QC Low	Benzoylecgonine 1	7 83	1 40	7 78	1 13	7 64	0 96	7 85	1 58	8 05	1 21	7 77	1 42	0 41
QC Mid	Benzoylecgonine 1	15 74	3 37	15 40	2 15	14 79	2 11	15 17	2 35	15 74	2 33	15 00	2 40	0 95
QC Mid	Benzoylecgonine 1	15 01	1 77	15 07	2 13	14 71	2 21	15 16	2 36	15 71	2 33	15 35	2 69	1 00
QC High	Cocaine 1	32 24	7 50	35 12	7 36	34 17	7 33	34 33	7 25	34 89	7 06	34 86	7 86	2 88
QC High	Cocaine 1	33 48	10 45	34 57	10 95	31 16	7 79	33 32	9 14	31 69	8 95	32 63	8 86	3 40
QC Low	Cocaine 1	8 10	1 42	8 14	1 39	7 83	1 13	8 20	1 78	8 19	1 65	8 09	1 54	0 38
QC Low	Cocaine 1	7 43	2 30	7 61	1 89	7 06	1 40	7 45	2 50	6 77	2 03	7 29	2 20	0 66
QC Mid	Cocaine 1	16 42	3 32	16 62	2 93	15 61	2 74	16 14	3 09	16 65	3 34	16 31	3 29	1 04
QC Mid	Cocaine 1	15 40	4 31	15 62	4 72	14 44	3 00	15 43	4 06	14 41	5 18	15 05	3 38	1 01
QC High	Morphine 1	62 11	14 30	69 47	16 49	63 22	16 07	66 21	16 86	68 59	14 67	68 23	16 22	7 36
QC High	Morphine 1	63 13	17 49	68 90	16 01	63 01	14 79	65 25	21 03	67 75	16 16	66 61	20 04	5 89
QC Low	Morphine 1	15 15	2 68	15 85	2 15	15 58	1 92	15 97	2 80	16 24	3 01	16 45	3 34	1 29
QC Low	Morphine 1	14 74	3 52	16 09	3 46	15 58	3 08	16 25	3 19	16 71	3 72	16 32	4 47	1 97
QC Mid	Morphine 1	30 15	5 07	32 14	5 26	30 11	5 02	31 40	8 67	32 15	5 35	32 16	6 61	2 05
QC Mid	Morphine 1	29 76	6 10	31 65	6 80	31 27	7 07	31 76	6 83	32 43	6 11	30 35	9 61	2 67
QC High	THC 1	12 80	3 63	13 83	3 24	13 44	3 13	13 06	3 10	13 19	3 22	13 64	3 84	0 84
QC High	THC 1	13 63	4 84	13 93	3 52	13 09	3 39	13 59	4 83	13 30	3 90	13 76	3 97	0 67
QC Low	THC 1	3 33	0 96	3 45	0 68	3 59	0 78	3 55	0 81	3 59	0 89	3 48	0 90	0 26
QC Low	THC 1	3 58	1 63	3 58	1 06	3 42	0 88	3 69	1 33	3 51	1 24	3 52	1 15	0 18
QC Mid	THC 1	6 39	1 54	6 54	1 42	6 40	1 16	6 35	1 31	6 51	1 32	6 25	1 38	0 26
QC Mid	THC 1	6 60	1 76	6 61	1 78	6 38	1 30	6 63	2 22	6 42	1 52	6 56	1 72	0 20

Attachment C1, Hair Proficiency Test Results for June 2020

Drugs of Abuse in Hair (DAH) Individual Report

DH029 - (Round 029) 22 Jun 2020

DH0057 - Averhealth

Issue Number: 1

Issued: 05/08/2020

Science
for a safer world

LGC Proficiency Testing
1 Chamberhall Business Park | Chamberhall Green | Bury | United Kingdom | BL9 0AP
-

Sample Details

Samples were despatched 11 May 2020

Reporting Deadline Date 22 June 2020

Participants are advised that for all analytes in these samples a large spread of submitted results has been observed In order to assess the results submitted by participants two assessments have been undertaken

The first is an assessment based upon whether the substances in the sample have been detected or not (Detected/Not detected)

The second assessment is based upon the concentration detected in combination with the reporting threshold Therefore, the assessment has been set based upon the spiked value which has come from homogeneity information and the difference between that and the reporting threshold divided by 3 and resulting in any laboratory having a z-score equal to or greater than 3 being unsatisfactory

Participants are recommended to determine whether the submitted results are acceptable to their own quality standards and acceptance criteria

The production of these samples was sub-contracted to Comedical s a s , Mattarello, Italy

Sample Details Sample 01

This sample was prepared from blank hair to produce a sample of cut hair with Morphine (1 353/mg), 6-MAM (0 864ng/mg), Codeine (1 087ng/mg) and Alprazolam (1 036ng/mg)

Analyte	Threshold
Morphine	0 2 ng/mg
6-MAM	0 2 ng/mg
Codeine	0 2 ng/mg
Alprazolam	0 05 ng/mg

Comments

Opiates (Morphine, 6-MAM, Codeine)

All laboratories who have submitted a result for 6-monoacetylmorphine have correctly reported the result as "Detected". One laboratory reported a concentration significantly below the reporting threshold and one reported a concentration greater than all other laboratories

All laboratories who have submitted a result for Codeine have correctly reported the result as "Detected". One laboratory reported a concentration significantly below the reporting threshold

All laboratories who have submitted a result for Morphine have correctly reported the result as "Detected" One laboratory reported a concentration significantly below the reporting threshold

All laboratories who have submitted a result for the Opiate Screening Group have correctly reported the result as "Detected".

Benzodiazepines (Alprazolam)

All laboratories who have submitted a result for Alprazolam have correctly reported the result as "Detected" One laboratory has submitted a result significantly greater than all other laboratories

One laboratory has reported a false negative result for the Benzodiazepine Screening Group This laboratory did not detect the presence of Alprazolam

One laboratory has submitted a false positive result for Nitrazepam

Sample Details Sample 02

This sample was prepared from blank hair to produce a sample of cut hair with Cocaine (1 069ng/mg), Benzoylecgonine (0 363ng/mg), Phenazepam (0 601ng/mg) and Methamfetamine (0 670ng/mg)

	Threshold
Cocaine	0 5 ng/mg
Benzoylecgonine	0 05 ng/mg
Phenazepam	0 05 ng/mg
Methamfetamine	0 2 ng/mg

Comments

Methamfetamine

The Amfetamine and Methamfetamine Screening Groups have not been assessed However, it should be noted that some laboratories reported a Not Detected finding for these but did report the presence of Methylamfetamine However, Laboratory DH030 is recommended to check whether their analysis is fit for their own purpose as they did not report the presence of either of these Screening Groups and also did not report for the presence of Methylamfetamine- therefore these findings suggest that in an actual case the presence of Methylamfetamine would not have been detected.

All laboratories who have submitted a result for Methyl-amfetamine have correctly reported the result as "Detected" One laboratory reported a concentration significantly below the reporting threshold

Cocaine and Metabolite (Cocaine & Benzoylecgonine)

All laboratories who have submitted a result for the Cocaine Screening Group have correctly reported the result as "Detected"

All laboratories who have submitted a result for Benzoylecgonine have correctly reported the result as "Detected". One laboratory reported a concentration significantly below the reporting threshold

All laboratories who have submitted a result for Cocaine have correctly reported the result as "Detected" One laboratory reported a concentration significantly below the reporting threshold and one reported a concentration greater than all other laboratories

Benzodiazepines (Phenazepam)

Two laboratories have submitted a false negative result for the Benzodiazepine Screening Group

No laboratories have submitted a result for Phenazepam

-

App: 98

Individual Report

This individual report contains a summary of all the results submitted and the performance assessment for your laboratory/individual analysts Please note that the nominated results for each analyte are indicated by the blue highlight in the analyst field

Full details of the scheme, sample types and data analysis can be found in the corresponding Main Report, along with any technical comments, if applicable The main report is the definitive version

If you have any questions regarding your results which are not answered in the Main Report, please contact us using the details provided on the front of the report If you would like to order any samples for re-testing please visit our web shop at www lgcstandards com or contact your local LGC representative

Results Summary

Sample	Results Reported	Satisfactory Results	Questionable Results	Unsatisfactory Results	Not Assessed
PT-DH-01	30	27	3	0	0
PT-DH-02	29	27	1	1	0
Round Total	59	54	4	1	0

a

Result which are Not Assessed should be review by comparing them with the assigned value and other relevant statistics given in the main report Participant, according to their internal quality criteria, may consider Not Assessed results to be satisfactory, questionable or unsatisfactory Further information regarding why results may not be assessed is given in the Scheme Information section of the main report

Please note surplus PT sample are available as QC materials once the round has closed These samples can be purchased at a reduced rate if you have taken this sample during the main round Visit our web shop at www lgcstandards com and search for the sample you require

For the following analytes you obtained an unsatisfactory result

Sample	Analyte
PT-DH-02	2 - Cocaine

For the following analytes you obtained an questionable result

Sample	Analyte
PT-DH-01	1 - Codeine
PT-DH-01	1 - Morphine
PT-DH-01	1 - 6-monoacetylmorphine
PT-DH-02	2 - Methyl-Amfetamine

App: 99

01 - DAH sample 1

Analyte	Analyst	Method	Result	Units	Z Score	Assigned Value	Ux AV	SDPA	Exp SDPA	Number of results	Median	Mean	Robust SD	SD	Your Reference
1 - 6-monoacetylmorphine	Lab Result	Other	0 361	ng/mg	-2 13*	0 864	0 084	0 2213	0 237	14	0 480	0 549	0 2417	0 2736	Other
1 - Alprazolam	Lab Result	Other	0 854	ng/mg	-0 51*	1 036	0 138	0 3286	0 356	6	0 780	0 720	0 2462	0 2022	Other
1 - Codeine	Lab Result	Other	0 259	ng/mg	-2 63*	1 087	0 109	0 2956	0 315	15	0 600	0 638	0 3381	0 3070	Other
1 - Hydrocodone	Lab Result	Other		ng/mg				N/A	N/A	0	N/A	N/A	N/A	N/A	Other
1 - Morphine	Lab Result	Other	0 355	ng/mg	-2 46*	1 353	0 131	0 3843	0 406	15	0 620	0 692	0 4049	0 3923	Other

* Please note, participant performance for this analyte has been assessed using a z' score, rather than a z score, in order to account for the measurement uncertainty of the assigned value which is not negligible when compared to the SDPA

Analyte	Result Field	Analyst	Method	Result	Assigned Value	Number of results	Satisfactory %	Your Reference
1 - 6-monoacetylmorphine	Detection	Lab Result	Other	Detected	Detected	16	100 0%	Other
1 - Alprazolam	Detection	Lab Result	Other	Detected	Detected	7	100 0%	Other
1 - Amfetamine	Detection	Lab Result	Other	Not Detected	Not Detected	13	100 0%	Other
1 - Benzoylecgonine	Detection	Lab Result	Other	Not Detected	Not Detected	12	100 0%	Other
1 - Clonazepam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
1 - Cocaine	Detection	Lab Result	Other	Not Detected	Not Detected	12	100 0%	Other
1 - Codeine	Detection	Lab Result	Other	Detected	Detected	16	100 0%	Other
1 - delta-9-THC	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
1 - Diazepam	Detection	Lab Result	Other	Not Detected	Not Detected	9	100 0%	Other
1 - Flunitrazepam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
1 - Hydrocodone	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
1 - Hydromorphone	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
1 - Lorazepam	Detection	Lab Result	Other	Not Detected	Not Detected	5	100 0%	Other
1 - MDA	Detection	Lab Result	Other	Not Detected	Not Detected	12	100 0%	Other
1 - MDEA	Detection	Lab Result	Other	Not Detected	Not Detected	9	100 0%	Other
1 - MDMA	Detection	Lab Result	Other	Not Detected	Not Detected	13	100 0%	Other
1 - Methyl-Amfetamine	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
1 - Midazolam	Detection	Lab Result	Other	Not Detected	Not Detected	3	100 0%	Other
1 - Morphine	Detection	Lab Result	Other	Detected	Detected	16	100 0%	Other
1 - Nordazepam	Detection	Lab Result	Other	Not Detected	Not Detected	8	100 0%	Other
1 - Oxazepam	Detection	Lab Result	Other	Not Detected	Not Detected	8	100 0%	Other
1 - Oxycodone	Detection	Lab Result	Other	Not Detected	Not Detected	6	100 0%	Other
1 - Oxymorphone	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
1 - Phencyclidine	Detection	Lab Result	Other	Not Detected	Not Detected	5	80 0%	Other
1 - Phentermine	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
1 - Temazepam	Detection	Lab Result	Other	Not Detected	Not Detected	5	100 0%	Other

02 - DAH sample 2

Analyte	Analyst	Method	Result	Units	Z Score	Assigned Value	Ux AV	SDPA	Exp SDPA	Number of results	Median	Mean	Robust SD	SD	Your Reference
2 - Methyl-Amfetamine	Lab Result	Other	0 318	ng/mg	-2 11*	0 670	0 059	0 156	0 167	14	0 505	0 462	0 1780	0 2624	Other
2 - Benzoylecgonine	Lab Result	Other	0 319	ng/mg	-0.40*	0 363	0 038	0 1043	0 111	15	0 240	0 244	0 1172	0 1221	Other
2 - Cocaine	Lab Result	Other	0 321	ng/mg	-3.95	1 069	0 056	0 1896	N/A	15	0 650	0 670	0 1502	0 2173	Other

* Please note, participant performance for this analyte has been assessed using a z' score, rather than a z score, in order to account for the measurement uncertainty of the assigned value which is not negligible when compared to the SDPA

Analyte	Result Field	Analyst	Method	Result	Assigned Value	Number of results	Satisfactory %	Your Reference
2 - Amfetamine	Detection	Lab Result	Other	Not Detected	Not Detected	12	100 0%	Other
2 - Methyl-Amfetamine	Detection	Lab Result	Other	Detected	Detected	15	100 0%	Other
2 - MDEA	Detection	Lab Result	Other	Not Detected	Not Detected	9	100 0%	Other
2 - MDMA	Detection	Lab Result	Other	Not Detected	Not Detected	13	100 0%	Other
2 - MDA	Detection	Lab Result	Other	Not Detected	Not Detected	12	100 0%	Other
2 - Phentermine	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
2 - Alprazolam	Detection	Lab Result	Other	Not Detected	Not Detected	6	100 0%	Other
2 - Clonazepam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
2 - Diazepam	Detection	Lab Result	Other	Not Detected	Not Detected	8	100 0%	Other
2 - Flunitrazepam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
2 - Lorazepam	Detection	Lab Result	Other	Not Detected	Not Detected	6	100 0%	Other
2 - Midazolam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
2 - Nordazepam	Detection	Lab Result	Other	Not Detected	Not Detected	8	100 0%	Other
2 - Oxazepam	Detection	Lab Result	Other	Not Detected	Not Detected	7	100 0%	Other
2 - Temazepam	Detection	Lab Result	Other	Not Detected	Not Detected	5	100 0%	Other
2 - delta-9-THC	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
2 - Benzoylecgonine	Detection	Lab Result	Other	Detected	Detected	16	100 0%	Other
2 - Cocaine	Detection	Lab Result	Other	Detected	Detected	16	100 0%	Other
2 - 6-monoacetylmorphine	Detection	Lab Result	Other	Not Detected	Not Detected	12	100 0%	Other
2 - Codeine	Detection	Lab Result	Other	Not Detected	Not Detected,	12	100 0%	Other
2 - Morphine	Detection	Lab Result	Other	Not Detected	Not Detected	12	100 0%	Other
2 - Hydromorphone	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
2 - Oxycodone	Detection	Lab Result	Other	Not Detected	Not Detected	7	100 0%	Other
2 - Hydrocodone	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
2 - Phencyclidine	Detection	Lab Result	Other	Not Detected	Not Detected	5	80 0%	Other
2 - Oxymorphone	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other

Attachment C2, Hair Proficiency Results for September 2020

Drugs of Abuse in Hair (DAH) Individual Report

DH030 - (Round 030) 28 Sep 2020

DH0057 - Averhealth

Issue Number 1

Issued: 02/10/2020

Science
for a safer world

LGC Proficiency Testing
1 Chamberhall Business Park | Chamberhall Green | Bury | United Kingdom | BL9 0AP

Sample Details

Samples were despatched 01 September 2020

Reporting Deadline Date 28 September 2020

Participants are advised that for all analytes in these samples a large spread of submitted results has been observed In order to assess the results submitted by participants two assessments have been undertaken

The first is an assessment based upon whether the substances in the sample have been detected or not (Detected/Not detected)

The second assessment is based upon the concentration detected in combination with the reporting threshold Therefore, the assessment has been set based upon the spiked value which has come from homogeneity information and the difference between that and the reporting threshold divided by 3 and resulting in any laboratory having a z-score equal to or greater than 3 being unsatisfactory Where the robust mean (median) is more than 25% away from the spiked value the robust mean will be used as the basis for assessment

Participants are recommended to determine whether the submitted results are acceptable to their own quality standards and acceptance criteria

The production of these samples was sub-contracted to Comedical s a s , Mattarello, Italy

Sample Details Sample 01

This sample was prepared from blank hair to produce a sample of cut hair with Amfetamine (1 38 ng/mg), Ketamine (1 33 ng/mg), Norketamine (0 71 ng mg) and Alprazolam (0.54 ng/mg)

Analyte	Threshold
Amfetamine	0 2 ng/mg
Ketamine	0 5 ng/mg
Norketamine	0 1 ng/mg
Alprazolam	0 05 ng/mg

Comments

Amfetamine

All laboratories who have submitted a result for Amfetamine have correctly reported the result as "Detected". All laboratories have reported an Amfetamine concentration greater than the threshold

All laboratories who have submitted a result for the Amfetamine Screening Group have correctly reported the result as "Detected".

Benzodiazepines (Alprazolam)

All laboratories who have submitted a result for Alprazolam have correctly reported the result as "Detected". One laboratory has submitted a result significantly greater than all other laboratories

The one laboratory who has reported a result for the Benzodiazepine Screening Group has incorrectly reported the result as "Not Detected"

Ketamine

All laboratories who have submitted a result for Ketamine have correctly reported the result as "Detected". All laboratories have reported a Ketamine concentration greater than the threshold One laboratory has submitted a result significantly greater than all other laboratories

All laboratories who have submitted a result for Norketamine have correctly reported the result as "Detected". One laboratory has submitted a result significantly greater than all other laboratories

Sample Details Sample 02

This sample was prepared from blank hair to produce a sample of cut hair with THC (0 30 ng/mg), THC-COOH (0 59 pg/mg), Cocaine (2 34 ng/mg), Benzoylecgonine (0 81 ng/mg)

App. 104

	Threshold
THC	0 05 ng/mg
THC-COOH	0 2 pg/mg
Cocaine	0 2 ng/mg
Benzoylecgonine	0 2 ng/mg

Comments

Cannabinoid (THC and THC-COOH)

All laboratories who have submitted a result for the Cannabinoid Screening Group have correctly reported the result as "Detected".

All laboratories who have submitted a result for delta-9-THC (THC) have correctly reported the result as "Detected" One laboratory has reported a result that is less than the reporting threshold for THC

All laboratories who have submitted a result for delta-9-THC-COOH (THC-COOH) have correctly reported the result as "Detected"

Cocaine and Metabolite (Cocaine & Benzoylecgonine)

All laboratories who have submitted a result for the Cocaine Screening Group have correctly reported the result as "Detected"

All laboratories who have submitted a result for Benzoylecgonine have correctly reported the result as "Detected".
One laboratory has reported a result that is less than the reporting threshold for benzoylecgonine

All laboratories who have submitted a result for Cocaine have correctly reported the result as "Detected" All laboratories have reported a result greater than the reporting threshold

-

Individual Report

This individual report contains a summary of all the results submitted and the performance assessment for your laboratory/individual analysts Please note that the nominated results for each analyte are indicated by the blue highlight in the analyst field

Full details of the scheme, sample types and data analysis can be found in the corresponding Main Report, along with any technical comments, if applicable The main report is the definitive version

If you have any questions regarding your results which are not answered in the Main Report, please contact us using the details provided on the front of the report If you would like to order any samples for re-testing please visit our web shop at www lgcstandards com or contact your local LGC representative

Results Summary

Sample	Results Reported	Satisfactory Results	Questionable Results	Unsatisfactory Results	Not Assessed
PT-DH-01	28	28	0	0	0
PT-DH-02	29	28	1	0	0
Round Total	57	56	1	0	0

a

Result which are Not Assessed should be review by comparing them with the assigned value and other relevant statistics given in the main report Participant, according to their internal quality criteria, may consider Not Assessed results to be satisfactory, questionable or unsatisfactory Further information regarding why results may not be assessed is given in the Scheme Information section of the main report

Please note surplus PT sample are available as QC materials once the round has closed These samples can be purchased at a reduced rate if you have taken this sample during the main round Visit our web shop at www lgcstandards com and search for the sample you require

No unsatisfactory results in this round

For the following analytes you obtained an questionable result

Sample	Analyte
PT-DH-02	2 - delta-9-THC

01 - DAH sample 1

Analyte	Analyst	Method	Result	Units	Z Score	Assigned Value	Ux AV	SDPA	Exp SDPA	Number of results	Median	Mean	Robust SD	SD	Your Reference
1 - 6-monoacetylmorphine	Lab Result	Other		ng/mg				N/A	N/A	0	N/A	N/A	N/A	N/A	Other
1 - Alprazolam	Lab Result	Other	0 587	ng/mg	0.29	0 540	0 033	0 1633	N/A	5	0 639	0 677	0 0526	0 1139	Other
1 - Amfetamine	Lab Result	Other	0 545	ng/mg	-0.53*	0 630	0 069	0 1433	0 159	13	0 630	0 644	0 2002	0 2232	Other

* Please note, participant performance for this analyte has been assessed using a z' score, rather than a z score, in order to account for the measurement uncertainty of the assigned value which is not negligible when compared to the SDPA

Analyte	Result Field	Analyst	Method	Result	Assigned Value	Number of results	Satisfactory %	Your Reference
1 - 6-monoacetylmorphine	Detection	Lab Result	Other	Not Detected	Not Detected	11	90 9%	Other
1 - Alprazolam	Detection	Lab Result	Other	Detected	Detected	5	100 0%	Other
1 - Amfetamine	Detection	Lab Result	Other	Detected	Detected	13	100 0%	Other
1 - Benzoylecgonine	Detection	Lab Result	Other	Not Detected	Not Detected	10	100 0%	Other
1 - Clonazepam	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
1 - Cocaine	Detection	Lab Result	Other	Not Detected	Not Detected	10	100 0%	Other
1 - Codeine	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
1 - delta-9-THC	Detection	Lab Result	Other	Not Detected	Not Detected	9	100 0%	Other
1 - Diazepam	Detection	Lab Result	Other	Not Detected	Not Detected	8	100 0%	Other
1 - Flunitrazepam	Detection	Lab Result	Other	Not Detected	Not Detected	3	100 0%	Other
1 - Hydrocodone	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
1 - Hydromorphone	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
1 - Lorazepam	Detection	Lab Result	Other	Not Detected	Not Detected	3	100 0%	Other
1 - MDA	Detection	Lab Result	Other	Not Detected	Not Detected	10	100 0%	Other
1 - MDEA	Detection	Lab Result	Other	Not Detected	Not Detected	6	100 0%	Other
1 - MDMA	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
1 - Methyl-Amfetamine	Detection	Lab Result	Other	Not Detected	Not Detected	8	100 0%	Other
1 - Midazolam	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
1 - Morphine	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
1 - Nordazepam	Detection	Lab Result	Other	Not Detected	Not Detected	8	100 0%	Other
1 - Oxazepam	Detection	Lab Result	Other	Not Detected	Not Detected	7	100 0%	Other
1 - Oxycodone	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
1 - Oxymorphone	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
1 - Phencyclidine	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
1 - Phentermine	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
1 - Temazepam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other

02 - DAH sample 2

Analyte	Analyst	Method	Result	Units	Z Score	Assigned Value	Ux AV	SDPA	Exp SDPA	Number of results	Median	Mean	Robust SD	SD	Your Reference
2 - delta-9-THC	Lab Result	Other	0 012	ng/mg	-2 75*	0 300	0 064	0 0833	0 105	11	0 369	0 342	0 1691	0 1527	Other
2 - Benzoylecgonine	Lab Result	Other	0 580	ng/mg	-1 13	0 810	0 051	0 2033	N/A	13	0 650	0 564	0 1468	0 2295	Other
2 - Cocaine	Lab Result	Other	0 581	ng/mg	-1 91*	1 480	0 202	0 4267	0 472	13	1 480	1 451	0 5813	0 6978	Other

* Please note, participant performance for this analyte has been assessed using a z' score, rather than a z score, in order to account for the measurement uncertainty of the assigned value which is not negligible when compared to the SDPA

Analyte	Result Field	Analyst	Method	Result	Assigned Value	Number of results	Satisfactory %	Your Reference
2 - Amfetamine	Detection	Lab Result	Other	Not Detected	Not Detected	10	100 0%	Other
2 - Methyl-Amfetamine	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
2 - MDEA	Detection	Lab Result	Other	Not Detected	Not Detected	6	100 0%	Other
2 - MDMA	Detection	Lab Result	Other	Not Detected	Not Detected	11	100 0%	Other
2 - MDA	Detection	Lab Result	Other	Not Detected	Not Detected	10	100 0%	Other
2 - Phentermine	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
2 - Alprazolam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
2 - Clonazepam	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
2 - Diazepam	Detection	Lab Result	Other	Not Detected	Not Detected	7	100 0%	Other
2 - Flunitrazepam	Detection	Lab Result	Other	Not Detected	Not Detected	3	100 0%	Other
2 - Lorazepam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
2 - Midazolam	Detection	Lab Result	Other	Not Detected	Not Detected	2	100 0%	Other
2 - Nordazepam	Detection	Lab Result	Other	Not Detected	Not Detected	7	100 0%	Other
2 - Oxazepam	Detection	Lab Result	Other	Not Detected	Not Detected	6	100 0%	Other
2 - Temazepam	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
2 - delta-9-THC	Detection	Lab Result	Other	Detected	Detected	11	100 0%	Other
2 - Benzoylecgonine	Detection	Lab Result	Other	Detected	Detected	13	100 0%	Other
2 - Cocaine	Detection	Lab Result	Other	Detected	Detected	13	100 0%	Other
2 - 6-monoacetylmorphine	Detection	Lab Result	Other	Not Detected	Not Detected	10	100 0%	Other
2 - Codeine	Detection	Lab Result	Other	Not Detected	Not Detected,	10	100 0%	Other
2 - Morphine	Detection	Lab Result	Other	Not Detected	Not Detected	9	100 0%	Other
2 - Hydromorphone	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
2 - Oxycodone	Detection	Lab Result	Other	Not Detected	Not Detected	5	100 0%	Other
2 - Hydrocodone	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other
2 - Phencyclidine	Detection	Lab Result	Other	Not Detected	Not Detected	4	100 0%	Other
2 - Oxymorphone	Detection	Lab Result	Other	Not Detected	Not Detected	1	100 0%	Other

Attachment D, LC-MS/MS Quality Control Policy

averhealth

LCMSMS QUALITY CONTROL

Written/Revised: *Michele Glinn | Laboratory Director*_____

Revision: *003 April 1, 2018*

Reviewed & Approved By:

*Dominique Delagnes | Chief Operating Officer*_____

Contents

LC-MS/MS Quality Control

Purpose

Describes quality control procedures for LC/MS/MS analyses.

Quantitation on LC/MS/MS

1 Each specimen batch (i.e. list of specimens submitted to the instrument for analysis) shall be calibrated for quantitation. On the LC-MS/MS instruments, quantitation is done in the MultiQuant program. Calibrators and controls must be prepared from NIST-traceable reference material or purchased from a vendor using NIST-traceable materials. Calibrators are generally designated as cutoff, 50% of the cutoff, 3x the cutoff, 5x the cutoff, 10x the cutoff, etc. The specific level and number of calibrators may vary with each analytical method. The lower limit of quantification is validated at the assay's lowest calibrator; the lower limit of reporting may be at or above the lowest calibrator for the assay.

2 Quantitation methods may be modified during the data analysis to account for shifts in retention time, variations in internal standard or calibrator recovery, or to select a better-fitting regression model. Default calibration curve regressions are generally set as linear or quadratic with 1/x weighting but may be changed by the operator to a None or $1/x^2$ regression if the resulting curve gives a better fit to the control data. One calibrator may be excluded by the operator if doing so gives a better fit to the control data. No more than 25% of the total number of data points per curve may be excluded without the laboratory director or designee's approval In instances of excluding the lowest or highest calibrator, data will be reviewed by the laboratory director or designee to ensure accurate result reporting outside of a truncated calibration set.

3 If the default curve is quadratic, but this gives a value of "no root" for a given analyte, a linear fit may be used for that analyte if the regression is acceptable. If the linear regression is not acceptable, a value of "> (limit of linearity)" will be reported.

4 Some assays will be reported in qualitative terms only (positive or negative). See individual methods for specific controls and acceptable reporting ranges.

5 Acceptable calibration back-fit bias (values calculated when a calibrator is included in the calibration model) shall not exceed +/- 15% except for the lower limit of quantification, which may have bias of +/- 20%.

Solutions & Standard Verification

Mobile Phases

Mobile phase preparation should be performed utilizing good laboratory technique. Glassware and glass bottles should be rinsed prior to use. Refer to individual assay standard operating procedures for mobile phase preparation. Prepared mobile phases should be loaded onto the system and the system lines purged of old solvents prior to use.

A system test is performed for each method prior to a batch run. This includes injections of a mobile phase blank with internal standard, a double blank (without internal standard) and the lowest calibrator. The test is valid if peaks are present for the respective retention times (RT) for each method with little/no background or interference. After a successful system test, a batch may be run on the instrument.

Standard and Control Preparation and Verification

Calibrators and controls will be prepared using certified reference materials from reputable vendors. All calibrators, controls and standard solutions will be prepared using Class A glassware, and calibrated pipettors. A calibrated microdispensor should be used for dispensing certified reference materials.

All standard solutions prepared in-house are matrix matched wherever possible. Urine calibrators and control solutions are prepared in synthetic urine and oral fluid calibrators and controls are made in synthetic saliva. Hair calibrators and controls will be made in synthetic urine but the procedure will include positive and negative extracted controls. Calibrator and control solutions for each assay shall be verified prior to use in analysis of patient samples. Verification of calibrators shall be performed by analyzing certified reference standards or previously analyzed proficiency test materials The values of the reference standards using the new calibrators should be within 15% of the target values. If the values are outside this limit, the analysis will be repeated using both current certified and new calibrators to determine if the variance is due to the standard itself or the new calibrator lot. If the variance is with the new calibrator lot, it will be discarded Verification of new controls will be done by analyzing them as unknowns using the current (certified) calibrators. Values should be within 15% of the target. If the values are outside of this range, the control will be discarded and a new solution made If, for either calibrators or controls, one drug in the cocktail is outside the acceptable range but the other drugs are acceptable, the target value for that drug may be adjusted for that lot with the laboratory director's approval.

Verification data will be reviewed by the laboratory director or designee before new lots are accepted. Records of verification data will be retained.

See individual analytical procedures for calibrator and control preparation details.

Internal Standards

Stable, isotopically labelled internal standards shall be used for verification of retention time, estimation of recovery efficiency, and evaluation of ion suppression.

1 In quantitative analyses of drugs, in biological matrices such as oral fluid or urine using liquid chromatography-tandem mass spectrometry (LC-MS/MS) methods, recovery is usually not 100%.
2 Decreases in recovery may result from losses during specimen preparation processes such as dilution, extraction and hydrolysis.
3 Endogenous substances in the specimen matrix can compete with analyte for binding sites in either extraction or may bind to the analyte of interest, reducing recoveries.
4 Some substances may co-elute with the analyte in liquid chromatography (LC) resulting in ionization suppression or ionization enhancement.
5 By choosing an appropriate internal standard (IS), the above-mentioned effects can be minimized since the analyte response is actually a measure of the relative signal produced by the analyte compared to that of the internal standard. Hence, selection of suitable internal standard material is crucial in LC-MS/MS. An ideal internal standard is a stable, isotopically labeled analog of the analyte to ensure parallel responses to analytical variations The highly correlated chemical and physical properties of these labeled analogs of the analyte will ensure that the same extraction recoveries, ionization responses and retention times are produced throughout the analysis. As such, use of isotopically labeled internal standards is a suitable mechanism by which ion suppression may be mediated. In a given analysis, however, an

internal standard may be substituted or omitted if the usual internal standard has a reduced recovery or chromatographic insufficiency

6 Internal standard recovery for all assays, unless specifically noted in the procedure for that assay, shall be 40 -125% of the mean recovery of the internal standards in the calibration curve and quality controls Specimens which demonstrate deviation from this range shall be reviewed by the laboratory director or designee. They may be re-prepped or re-injected as appropriate.

Controls

Control specimens for each analyte shall be run with each batch. See individual procedures for details

1 At least two distinct levels of controls will be run Controls may be made in-house or purchased from an external source. Controls prepared in-house will be made separately from calibrators, from a different lot of stock materials wherever possible, otherwise prepared on a different day and from a different ampoule. Controls will be verified as described above. See individual method procedures for details
2 Controls will be matrix-matched wherever possible.
3 A blank consisting of negative matrix will also be run.
4 A control to monitor the performance of the enzyme hydrolysis will also be used in assays requiring hydrolysis, and in which a suitable glucuronidated drug standard is available. This control will contain one or more compounds, characteristic of the panel, in glucuronide form.
5 Recovery of the free drug will be monitored It is expected that hydrolytic efficiency may vary with enzyme lot, between individual specimens as a function of matrix effects, and between drugs in any given specimen. If the characteristic recovery decreases dramatically or suddenly, a root cause investigation will be initiated, and appropriate corrective action taken.
6 Control performance will be reviewed at least monthly by the laboratory director or designee

Peak Integration

Data analysts shall integrate all peaks in the Multiquant program according to the quantitation method parameters, and then review the data for correct peak integration.

1 Acceptable peak integration is from trough to trough at the baseline, including fronting or tailing as appropriate Integration of fronting or tailing peaks shall be consistent with internal standard integration.
2 The operator shall review the peak integrations before accepting the data, and may manually correct the integrations if one of the following applies. (a) the peak is not completely integrated (b) the peak is overly integrated, i e too much of the baseline past the trough is included in the integration (c) the wrong peak is integrated (d) shoulder or side peaks are integrated along with the main peak or (e) two peaks are overlapping and the data processing method has not properly resolved them.

Transition Ratio Analysis

A sophisticated software system assists the data review. The built-in flagging capabilities in MultiQuant™ 3.0 software allow the user to set both upper and lower concentration limits for every analyte in a method. The lower limit and upper limit of the calculated concentration can be defined directly in the quantitation method editor. Unknown samples having measured concentrations outside of the specified concentration limits are automatically highlighted in the results table.

The qualifier/quantifier ion ratio matches the expected ion ratio, and therefore confirms the identity of the compound The default tolerance for confirmation is ± 20% of the derived ion ratio. Ratios outside this may indicate the presence of an interferent and should be reviewed by a supervisor.

Data Processing

1. The data shall be reprocessed, and acceptable control values obtained before the results for that analyte from that specimen batch can be reported.
2. The laboratory technician shall review the calibrator, control and unknown specimen data to ensure that it is accurate and valid prior to accepting it.
3. The performance of the calibrators and controls and their review by the laboratory technician shall be documented. Statistical analysis of imprecision and control performance will be reviewed periodically by the laboratory director or designee.
4. See individual methods for details on numbers of controls required and acceptable performance specifications.

Sending Results to Aversys

Refer to Aversys Policy

Repeat Analyses

For any specimen result that does not meet the criteria outlined in the LC-MSMS Quality Control procedures outlined above or in the individual analytical procedures, the specimen will either be reinjected ore re-aliquotted for repeat analysis.

Re-injecting a Specimen

Re-injecting may be performed for any of the following reasons within 24 hours of the original sample preparation

1. Instrument/acquisition error batch does not complete analysis
2. To rule out potential carryover from previous specimen
3. Poor chromatography for an individual specimen with QC, Standards, and Blanks all acceptable

4 Transition retention times for specimen >0.01min difference
5 Transition concentrations are reading an ion ratio error after allowable manual integration

Re-aliquoting a Specimen

Re-aliquoting and re-preparing a specimen may be done for any of the following reasons

1 Unacceptable QC, curve, or standards
2 Poor chromatography throughout batch
3 Specimen requires dilution to obtain recordable quantitation

Dilution

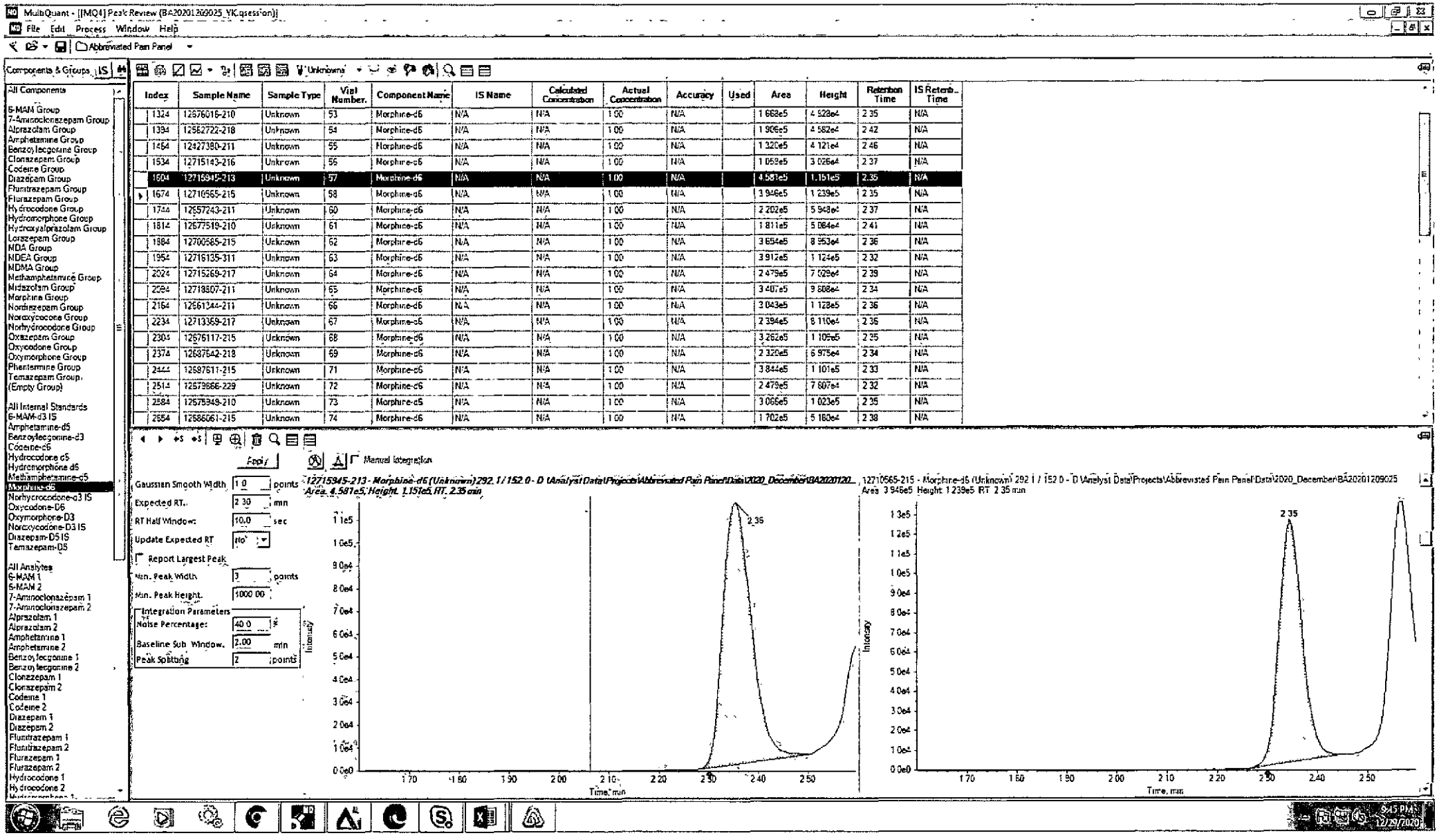
If specimens are above the Analytical Measurement Range, they may be diluted and re-analyzed, and the final concentration calculated by application of the dilution level. Specimens will be diluted to a necessary concentration to obtain a quantitation below our ULOL. Generally specimens will only be diluted and re-analyzed if they require precise concentration levels or upon customer request.

Tracking

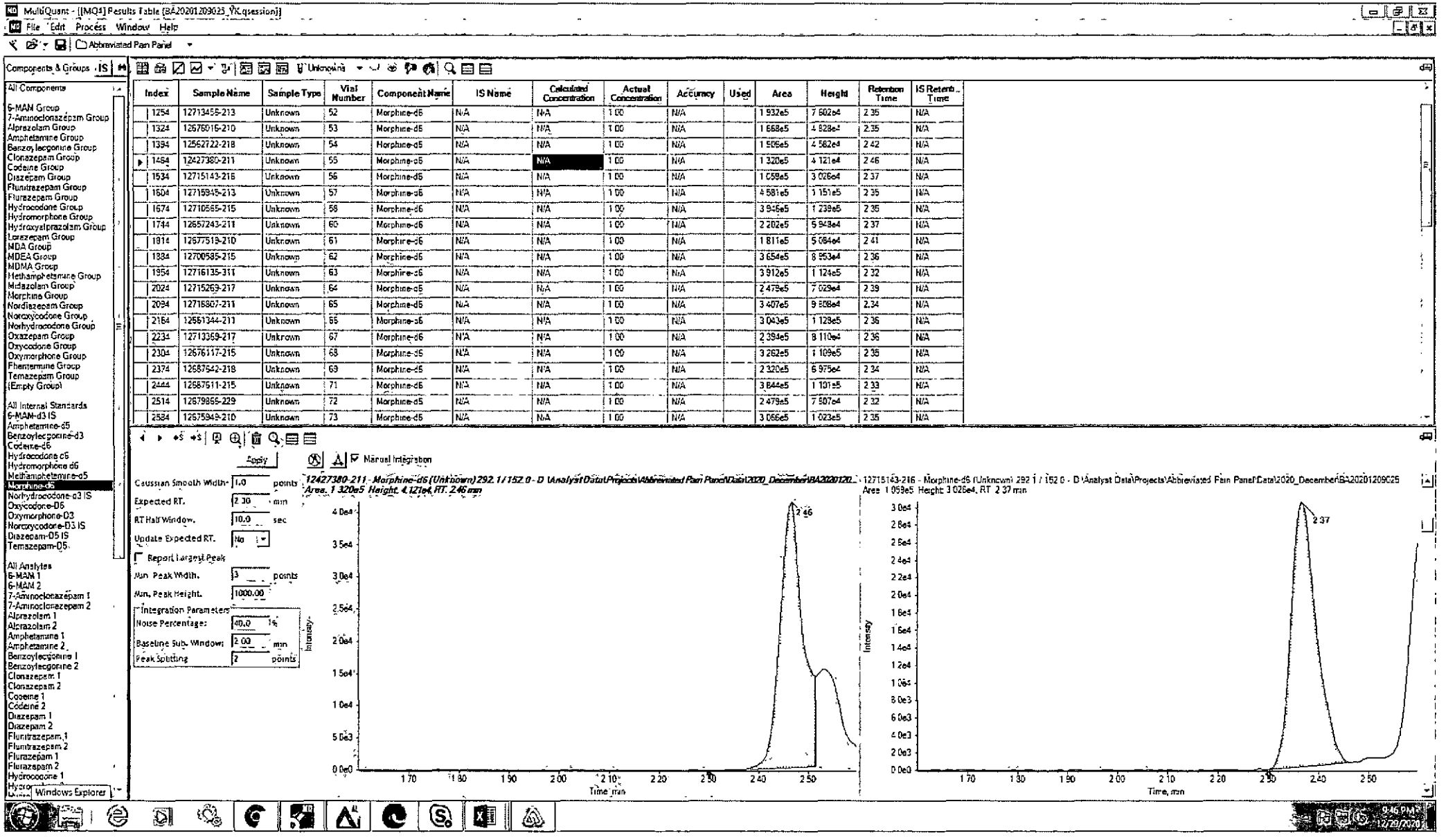
The identities of the technicians who prepared the sample and reviewed and released the data, and the instrument used, will be recorded

Version	Title	Date	Initials
1	LCMSMS Procedures	July 2015	
2	CAP General Procedures	March 2016	

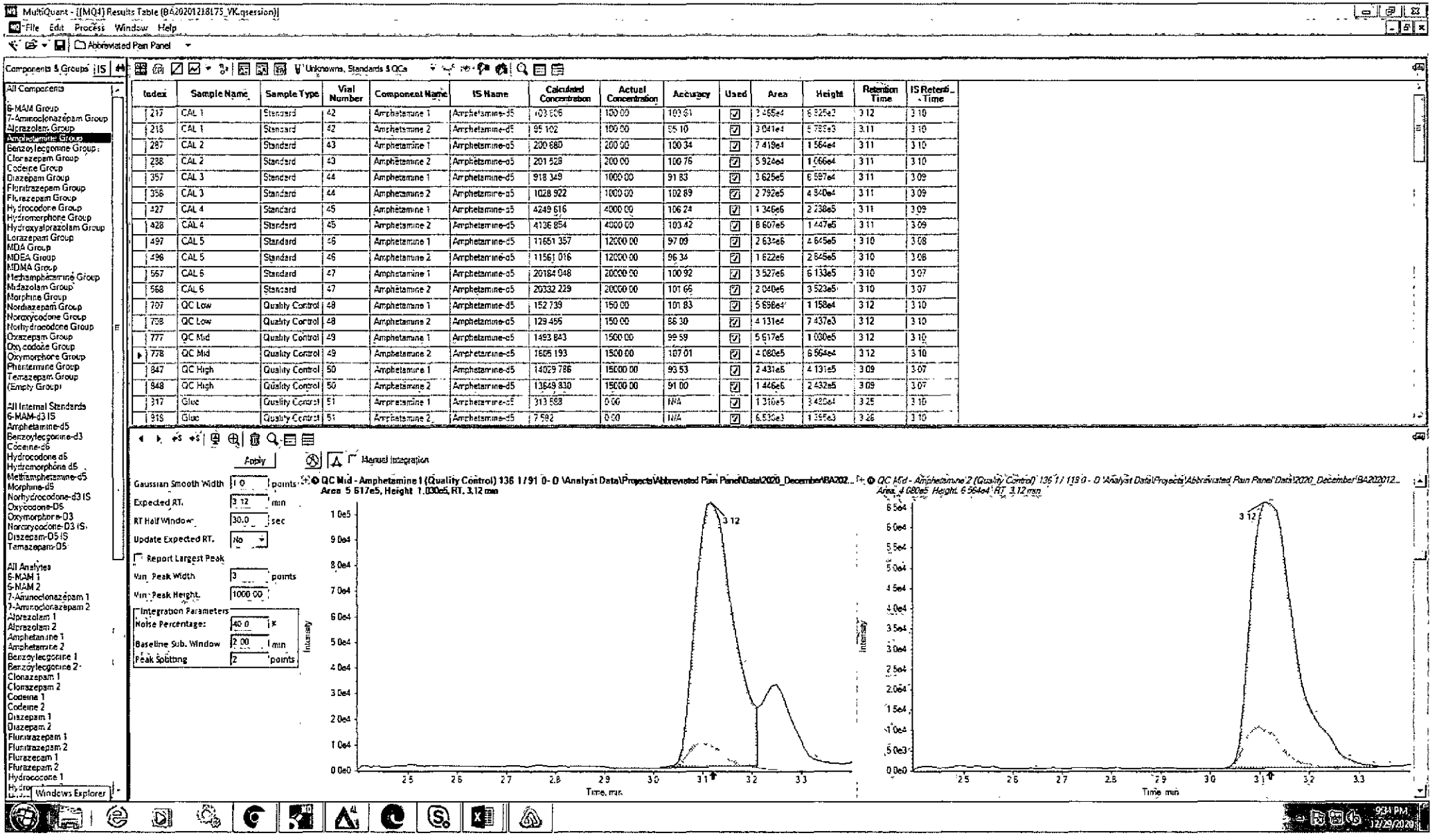
Attachment E1 to E11, Examples of Manual Integration



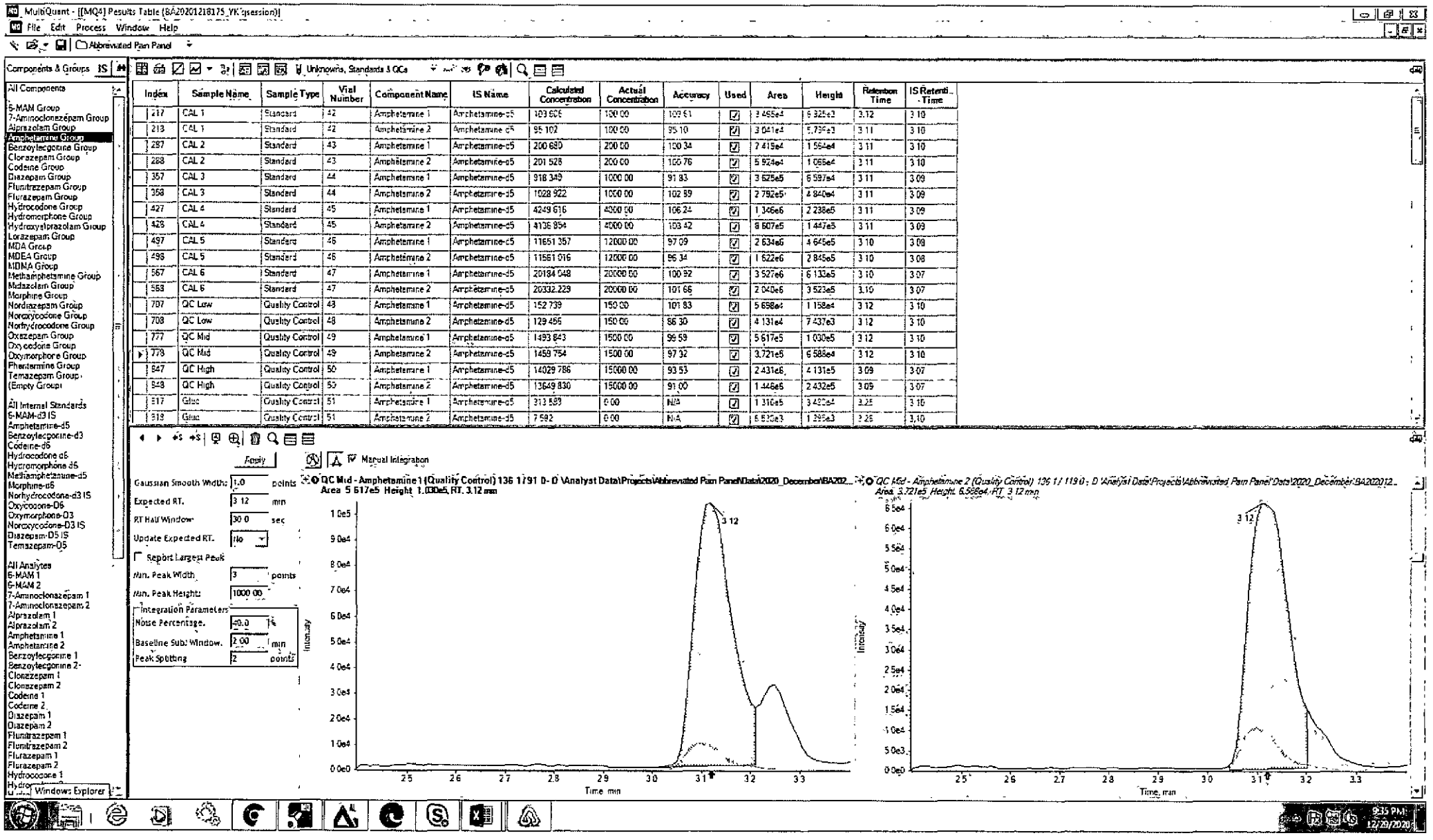
Index	Sample Name	Sample Type	Vial Number	Component Name	IS Name	Calculated Concentration	Actual Concentration	Accuracy	Used	Area	Height	Retention Time	IS Retent... Time
1324	12676016-210	Unknown	53	Morphine-d6	N/A	N/A	1.00	N/A		1.668e5	4.928e4	2.35	N/A
1394	12562722-218	Unknown	54	Morphine-d6	N/A	N/A	1.00	N/A		1.906e5	4.582e4	2.42	N/A
1464	12427380-211	Unknown	55	Morphine-d6	N/A	N/A	1.00	N/A		1.320e5	4.121e4	2.46	N/A
1534	12715143-216	Unknown	56	Morphine-d6	N/A	N/A	1.00	N/A		1.059e5	3.026e4	2.37	N/A
1604	12715945-213	Unknown	57	Morphine-d6	N/A	N/A	1.00	N/A		4.581e5	1.151e5	2.35	N/A
1674	12710565-215	Unknown	58	Morphine-d6	N/A	N/A	1.00	N/A		3.946e5	1.239e5	2.35	N/A
1744	12557243-211	Unknown	60	Morphine-d6	N/A	N/A	1.00	N/A		2.202e5	5.948e4	2.37	N/A
1814	12677519-210	Unknown	61	Morphine-d6	N/A	N/A	1.00	N/A		1.811e5	5.084e4	2.41	N/A
1884	12700585-215	Unknown	62	Morphine-d6	N/A	N/A	1.00	N/A		3.654e5	8.953e4	2.36	N/A
1954	12716135-311	Unknown	63	Morphine-d6	N/A	N/A	1.00	N/A		3.912e5	1.124e5	2.32	N/A
2024	12715269-217	Unknown	64	Morphine-d6	N/A	N/A	1.00	N/A		2.479e5	7.029e4	2.39	N/A
2094	12718507-211	Unknown	65	Morphine-d6	N/A	N/A	1.00	N/A		3.407e5	9.808e4	2.34	N/A
2164	12661344-211	Unknown	66	Morphine-d6	N/A	N/A	1.00	N/A		3.043e5	1.128e5	2.36	N/A
2234	12713369-217	Unknown	67	Morphine-d6	N/A	N/A	1.00	N/A		2.394e5	6.110e4	2.35	N/A
2304	12676117-215	Unknown	68	Morphine-d6	N/A	N/A	1.00	N/A		3.262e5	1.105e5	2.35	N/A
2374	12687542-218	Unknown	69	Morphine-d6	N/A	N/A	1.00	N/A		2.320e5	6.975e4	2.34	N/A
2444	12597611-215	Unknown	71	Morphine-d6	N/A	N/A	1.00	N/A		3.844e5	1.101e5	2.33	N/A
2514	12579666-229	Unknown	72	Morphine-d6	N/A	N/A	1.00	N/A		2.479e5	7.607e4	2.32	N/A
2584	12575949-210	Unknown	73	Morphine-d6	N/A	N/A	1.00	N/A		3.066e5	1.023e5	2.35	N/A
2654	12586061-215	Unknown	74	Morphine-d6	N/A	N/A	1.00	N/A		1.702e5	5.180e4	2.38	N/A



Index	Sample Name	Sample Type	Vial Number	Component Name	IS Name	Calculated Concentration	Actual Concentration	Accuracy	Used	Area	Height	Retention Time	IS Retenti... Time
1254	12713458-213	Unknown	52	Morphine-d6	N/A	N/A	1.00	N/A		1.932e5	7.602e4	2.35	N/A
1324	12676016-210	Unknown	53	Morphine-d6	N/A	N/A	1.00	N/A		1.668e5	4.928e4	2.35	N/A
1394	12562722-218	Unknown	54	Morphine-d6	N/A	N/A	1.00	N/A		1.505e5	4.582e4	2.42	N/A
1464	12427380-211	Unknown	55	Morphine-d6	N/A	N/A	1.00	N/A		1.320e5	4.121e4	2.46	N/A
1534	12715143-216	Unknown	56	Morphine-d6	N/A	N/A	1.00	N/A		1.059e5	3.026e4	2.37	N/A
1604	12715945-213	Unknown	57	Morphine-d6	N/A	N/A	1.00	N/A		4.581e5	1.151e5	2.35	N/A
1674	12710585-215	Unknown	58	Morphine-d6	N/A	N/A	1.00	N/A		3.936e5	1.239e5	2.35	N/A
1744	12657243-211	Unknown	60	Morphine-d6	N/A	N/A	1.00	N/A		2.202e5	5.948e4	2.37	N/A
1814	12677519-210	Unknown	61	Morphine-d6	N/A	N/A	1.00	N/A		1.811e5	5.084e4	2.41	N/A
1884	12700585-215	Unknown	62	Morphine-d6	N/A	N/A	1.00	N/A		3.654e5	8.953e4	2.36	N/A
1954	12716135-311	Unknown	63	Morphine-d6	N/A	N/A	1.00	N/A		3.912e5	1.124e5	2.32	N/A
2024	12715269-217	Unknown	64	Morphine-d6	N/A	N/A	1.00	N/A		2.479e5	7.029e4	2.39	N/A
2094	12716807-211	Unknown	65	Morphine-d6	N/A	N/A	1.00	N/A		3.407e5	9.808e4	2.34	N/A
2164	12561344-211	Unknown	66	Morphine-d6	N/A	N/A	1.00	N/A		3.043e5	1.128e5	2.36	N/A
2234	12713369-217	Unknown	67	Morphine-d6	N/A	N/A	1.00	N/A		2.394e5	8.110e4	2.36	N/A
2304	12676117-215	Unknown	68	Morphine-d6	N/A	N/A	1.00	N/A		3.262e5	1.109e5	2.35	N/A
2374	12687542-218	Unknown	69	Morphine-d6	N/A	N/A	1.00	N/A		2.320e5	6.975e4	2.34	N/A
2444	12687511-215	Unknown	71	Morphine-d6	N/A	N/A	1.00	N/A		3.844e5	1.101e5	2.33	N/A
2514	12679866-229	Unknown	72	Morphine-d6	N/A	N/A	1.00	N/A		2.479e5	7.507e4	2.32	N/A
2584	12675949-210	Unknown	73	Morphine-d6	N/A	N/A	1.00	N/A		3.066e5	1.023e5	2.35	N/A



Index	Sample Name	Sample Type	Vial Number	Component Name	IS Name	Calculated Concentration	Actual Concentration	Accuracy	Used	Area	Height	Retention Time	IS Retenti... Time
217	CAL 1	Standard	42	Amphetamine 1	Amphetamine-d5	103.606	100.00	103.61	☑	2.465e4	6.925e3	3.12	3.10
218	CAL 1	Standard	42	Amphetamine 2	Amphetamine-d5	95.102	100.00	95.10	☑	3.041e4	6.783e3	3.11	3.10
287	CAL 2	Standard	43	Amphetamine 1	Amphetamine-d5	200.680	200.00	100.34	☑	7.419e4	1.564e4	3.11	3.10
288	CAL 2	Standard	43	Amphetamine 2	Amphetamine-d5	201.528	200.00	100.76	☑	5.926e4	1.066e4	3.11	3.10
357	CAL 3	Standard	44	Amphetamine 1	Amphetamine-d5	918.349	1000.00	91.83	☑	3.625e5	6.587e4	3.11	3.09
358	CAL 3	Standard	44	Amphetamine 2	Amphetamine-d5	1028.922	1000.00	102.89	☑	2.792e5	4.840e4	3.11	3.09
427	CAL 4	Standard	45	Amphetamine 1	Amphetamine-d5	4249.616	4000.00	106.24	☑	1.346e6	2.238e5	3.11	3.09
428	CAL 4	Standard	45	Amphetamine 2	Amphetamine-d5	4136.854	4000.00	103.42	☑	8.607e5	1.447e5	3.11	3.09
497	CAL 5	Standard	46	Amphetamine 1	Amphetamine-d5	11651.357	12000.00	97.09	☑	2.632e6	2.645e5	3.10	3.08
498	CAL 5	Standard	46	Amphetamine 2	Amphetamine-d5	11561.016	12000.00	96.34	☑	1.622e6	2.645e5	3.10	3.08
567	CAL 6	Standard	47	Amphetamine 1	Amphetamine-d5	20184.048	20000.00	100.92	☑	3.527e6	6.133e5	3.10	3.07
568	CAL 6	Standard	47	Amphetamine 2	Amphetamine-d5	20332.229	20000.00	101.66	☑	2.040e6	3.523e5	3.10	3.07
707	QC Low	Quality Control	48	Amphetamine 1	Amphetamine-d5	152.739	150.00	101.83	☑	5.698e4	1.158e4	3.12	3.10
708	QC Low	Quality Control	48	Amphetamine 2	Amphetamine-d5	129.456	150.00	86.30	☑	4.131e4	7.437e3	3.12	3.10
777	QC Mid	Quality Control	49	Amphetamine 1	Amphetamine-d5	1493.843	1500.00	99.59	☑	5.617e5	1.030e5	3.12	3.10
778	QC Mid	Quality Control	49	Amphetamine 2	Amphetamine-d5	1605.193	1500.00	107.01	☑	4.080e5	6.564e4	3.12	3.10
847	QC High	Quality Control	50	Amphetamine 1	Amphetamine-d5	14029.786	15000.00	93.53	☑	2.431e5	4.131e5	3.09	3.07
848	QC High	Quality Control	50	Amphetamine 2	Amphetamine-d5	13649.830	15000.00	91.00	☑	1.446e6	2.432e5	3.09	3.07
917	Gluc	Quality Control	51	Amphetamine 1	Amphetamine-d5	313.593	0.00	N/A	☑	1.316e5	3.480e4	3.25	3.10
918	Gluc	Quality Control	51	Amphetamine 2	Amphetamine-d5	7.592	0.00	N/A	☑	6.530e3	1.395e3	3.26	3.10


MultiQuant - [[MQ4] Results Table (BA20201218175_YK.qsession)]
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Abbreviated Pain Panel
Components & Groups IS
Unknowns, Standards & QCs
Index Sample Name Sample Type Vial Number Component Name IS Name Calculated Concentration Actual Concentration Accuracy Used Area Height Retention Time IS Retenti.. Time
217 CAL 1 Standard 42 Amphetamine 1 Amphetamine-d5 103 606 100 00 103 61 3 455e4 6 325e3 3 12 3 10
218 CAL 1 Standard 42 Amphetamine 2 Amphetamine-d5 95 102 100 00 95 10 3 041e4 5 739e3 3 11 3 10
287 CAL 2 Standard 43 Amphetamine 1 Amphetamine-d5 200 680 200 00 100 34 7 415e4 1 564e4 3 11 3 10
288 CAL 2 Standard 43 Amphetamine 2 Amphetamine-d5 201 528 200 00 100 76 5 924e4 1 066e4 3 11 3 10
357 CAL 3 Standard 44 Amphetamine 1 Amphetamine-d5 918 349 1000 00 91 83 3 625e5 6 597e4 3 11 3 09
358 CAL 3 Standard 44 Amphetamine 2 Amphetamine-d5 1028 922 1000 00 102 89 2 792e5 4 840e4 3 11 3 09
427 CAL 4 Standard 45 Amphetamine 1 Amphetamine-d5 4249 616 4000 00 106 24 1 346e6 2 238e5 3 11 3 09
428 CAL 4 Standard 45 Amphetamine 2 Amphetamine-d5 4136 854 4000 00 103 42 9 807e5 1 447e5 3 11 3 09
497 CAL 5 Standard 46 Amphetamine 1 Amphetamine-d5 11651 357 12000 00 97 09 2 634e6 4 645e5 3 10 3 08
498 CAL 5 Standard 46 Amphetamine 2 Amphetamine-d5 11561 016 12000 00 96 34 1 622e6 2 845e5 3 10 3 08
567 CAL 6 Standard 47 Amphetamine 1 Amphetamine-d5 20184 048 20000 00 100 92 3 527e6 6 133e5 3 10 3 07
568 CAL 6 Standard 47 Amphetamine 2 Amphetamine-d5 20332 229 20000 00 101 66 2 040e6 3 523e5 3 10 3 07
707 QC Low Quality Control 48 Amphetamine 1 Amphetamine-d5 152 739 150 00 101 83 5 698e4 1 158e4 3 12 3 10
708 QC Low Quality Control 48 Amphetamine 2 Amphetamine-d5 129 456 150 00 86 30 4 131e4 7 437e3 3 12 3 10
777 QC Mid Quality Control 49 Amphetamine 1 Amphetamine-d5 1493 843 1500 00 99 59 5 617e5 1 030e5 3 12 3 10
778 QC Mid Quality Control 49 Amphetamine 2 Amphetamine-d5 1459 754 1500 00 97 32 3 721e5 6 588e4 3 12 3 10
847 QC High Quality Control 50 Amphetamine 1 Amphetamine-d5 14029 786 15000 00 93 53 2 431e6 4 131e5 3 09 3 07
848 QC High Quality Control 50 Amphetamine 2 Amphetamine-d5 13649 830 15000 00 91 00 1 446e6 2 432e5 3 09 3 07
917 Glue Quality Control 51 Amphetamine 1 Amphetamine-d5 313 583 0 00 N/A 1 310e5 3 492e4 3 25 3 10
918 Glue Quality Control 51 Amphetamine 2 Amphetamine-d5 7 582 0 00 N/A 6 820e3 1 299e3 3 26 3 10
Apply
Manual Integration
Gaussian Smooth Width: 1.0 points
Expected RT: 3 12 min
RT Half Window: 30 0 sec
Update Expected RT: No
Report Largest Peak
Min. Peak Width: 3 points
Min. Peak Height: 1000 00
Integration Parameters
Noise Percentage: 40.0 %
Baseline Sub Window: 2 00 min
Peak Spotting: 2 points
QC Mid - Amphetamine 1 (Quality Control) 136 1791 0- D:\Analyst Data\Projects\Abbreviated Pain Panel\Data\2020_December\BA202...
Area: 5 617e5 Height: 1.030e5 RT: 3.12 min
QC Mid - Amphetamine 2 (Quality Control) 136 1791 0 - D:\Analyst Data\Projects\Abbreviated Pain Panel\Data\2020_December\BA202012...
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Intensity
Time, min
All Components
6-MAM Group
7-Aminoclonazepam Group
Alprazolam Group
Amphetamine Group
Benzoylecgonine Group
Clonazepam Group
Codeine Group
Diazepam Group
Flunitrazepam Group
Flurazepam Group
Hydrocodone Group
Hydromorphone Group
Hydroxyalprazolam Group
Lorazepam Group
MDA Group
MDEA Group
MDMA Group
Methamphetamine Group
Midazolam Group
Morphine Group
Nordiazepam Group
Noroxycodone Group
Norhydrocodone Group
Oxazepam Group
Oxycodone Group
Oxymorphone Group
Phentermine Group
Temazepam Group
(Empty Group)
All Internal Standards
6-MAM-d3 IS
Amphetamine-d5
Benzoylecgonine-d3
Codeine-d6
Hydrocodone-d6
Hydromorphone-d6
Methamphetamine-d5
Morphine-d6
Norhydrocodone-d3 IS
Oxycodone-D6
Oxymorphone-D3
Noroxycodone-D3 IS
Diazepam-D5 IS
Temazepam-D5
All Analytes
6-MAM 1
6-MAM 2
7-Aminoclonazepam 1
7-Aminoclonazepam 2
Alprazolam 1
Alprazolam 2
Amphetamine 1
Amphetamine 2
Benzoylecgonine 1
Benzoylecgonine 2
Clonazepam 1
Clonazepam 2
Codeine 1
Codeine 2
Diazepam 1
Diazepam 2
Flunitrazepam 1
Flunitrazepam 2
Flurazepam 1
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Hydrocodone 1
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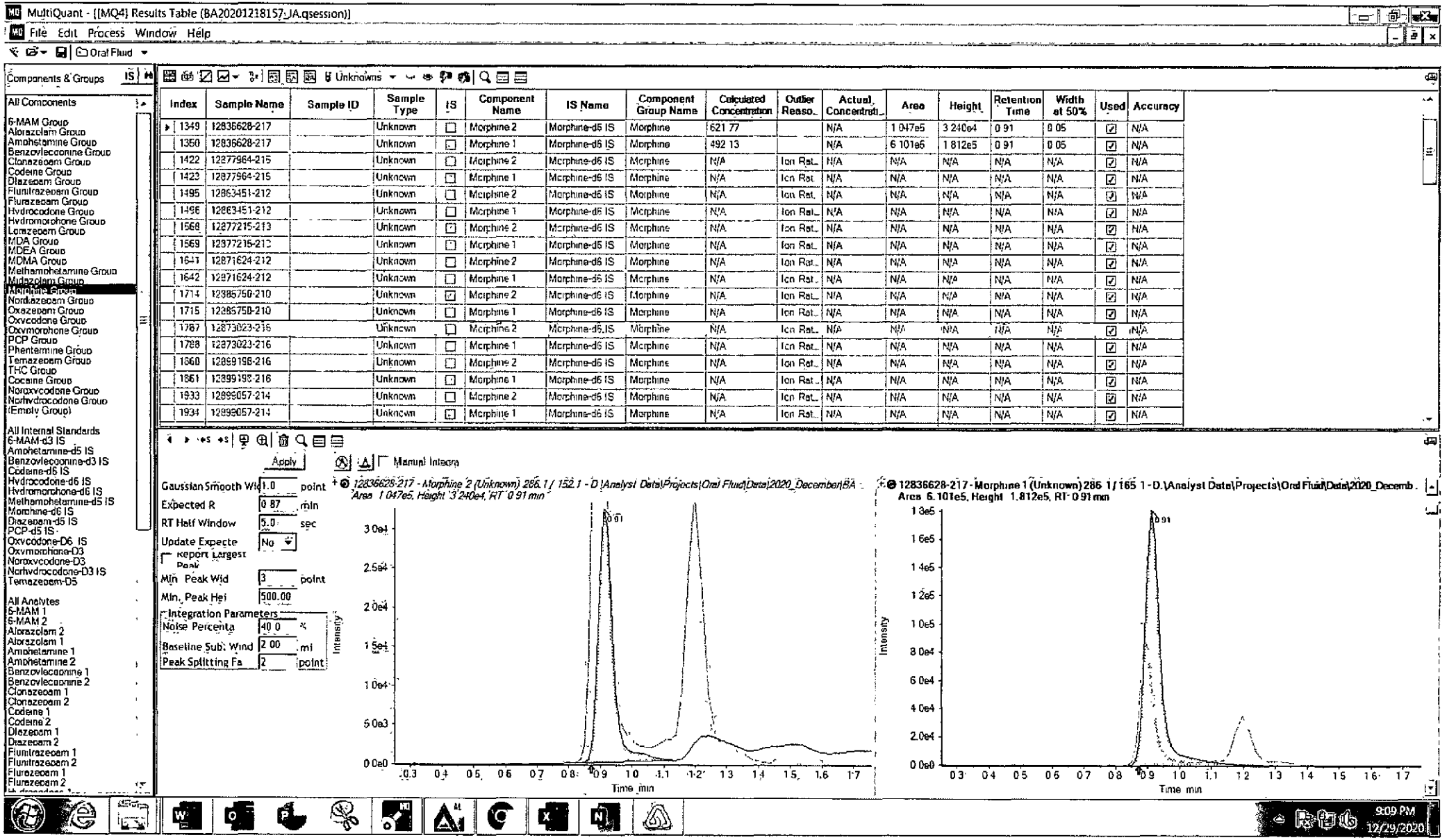
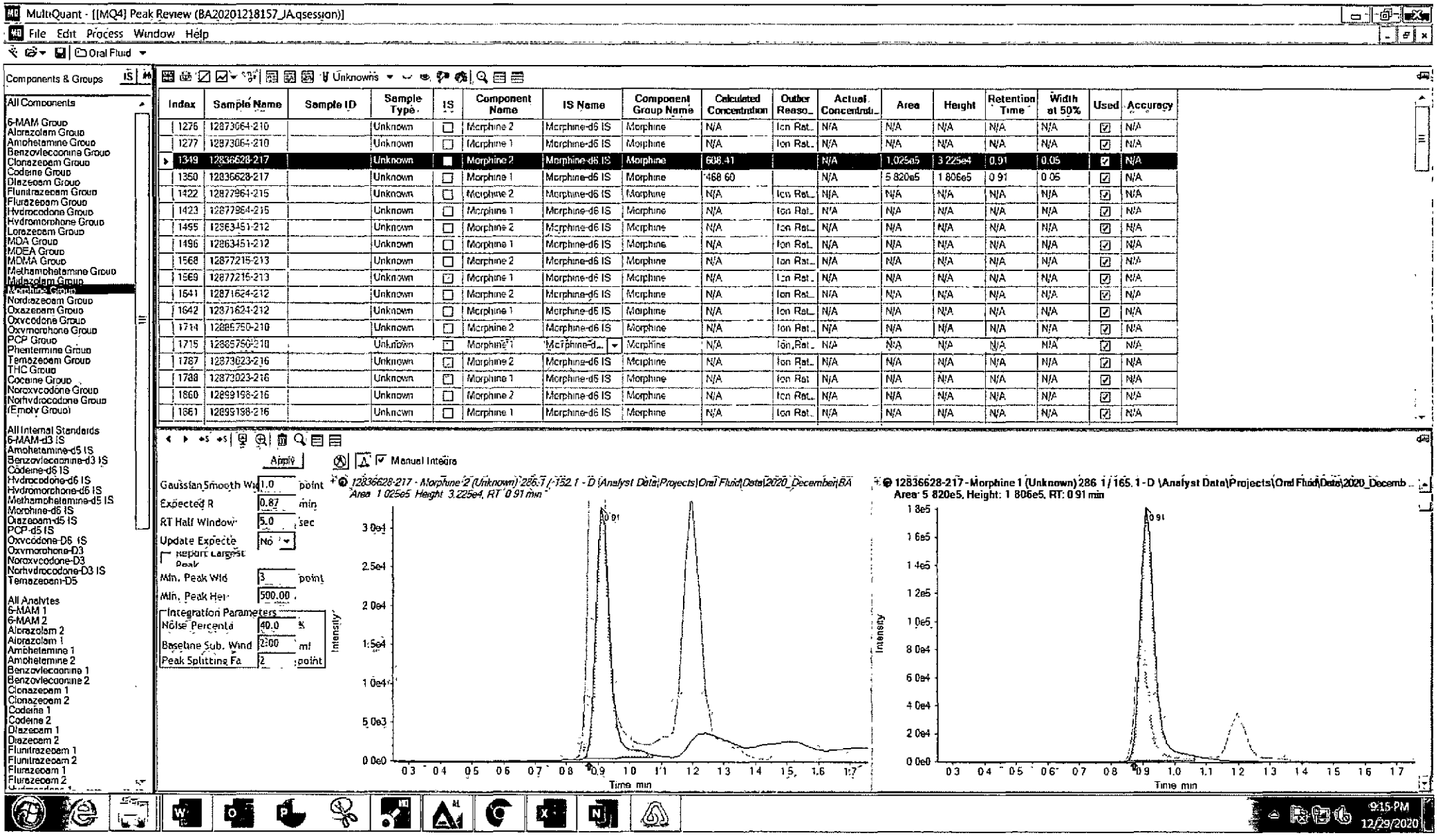
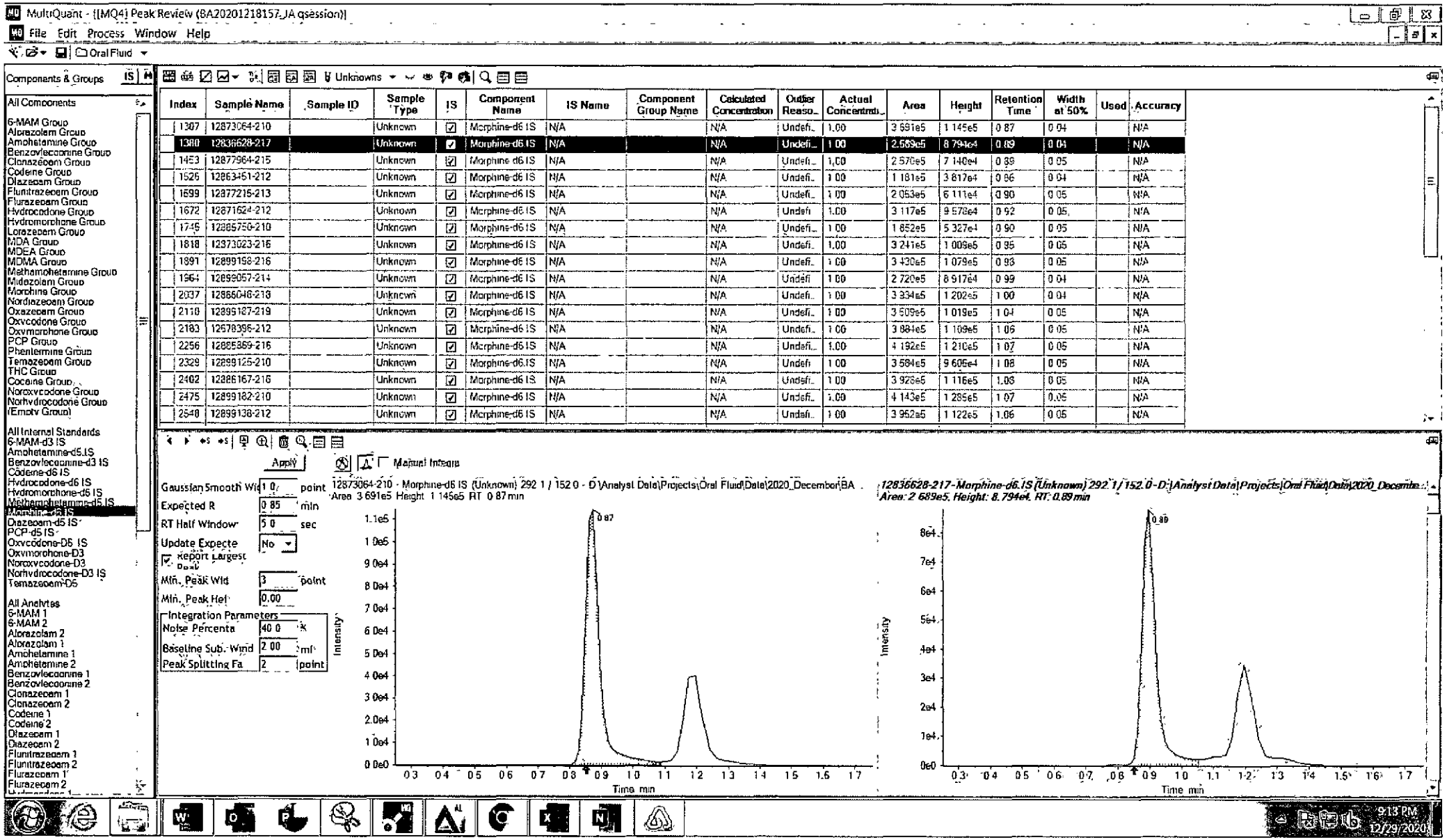
12/20/2020



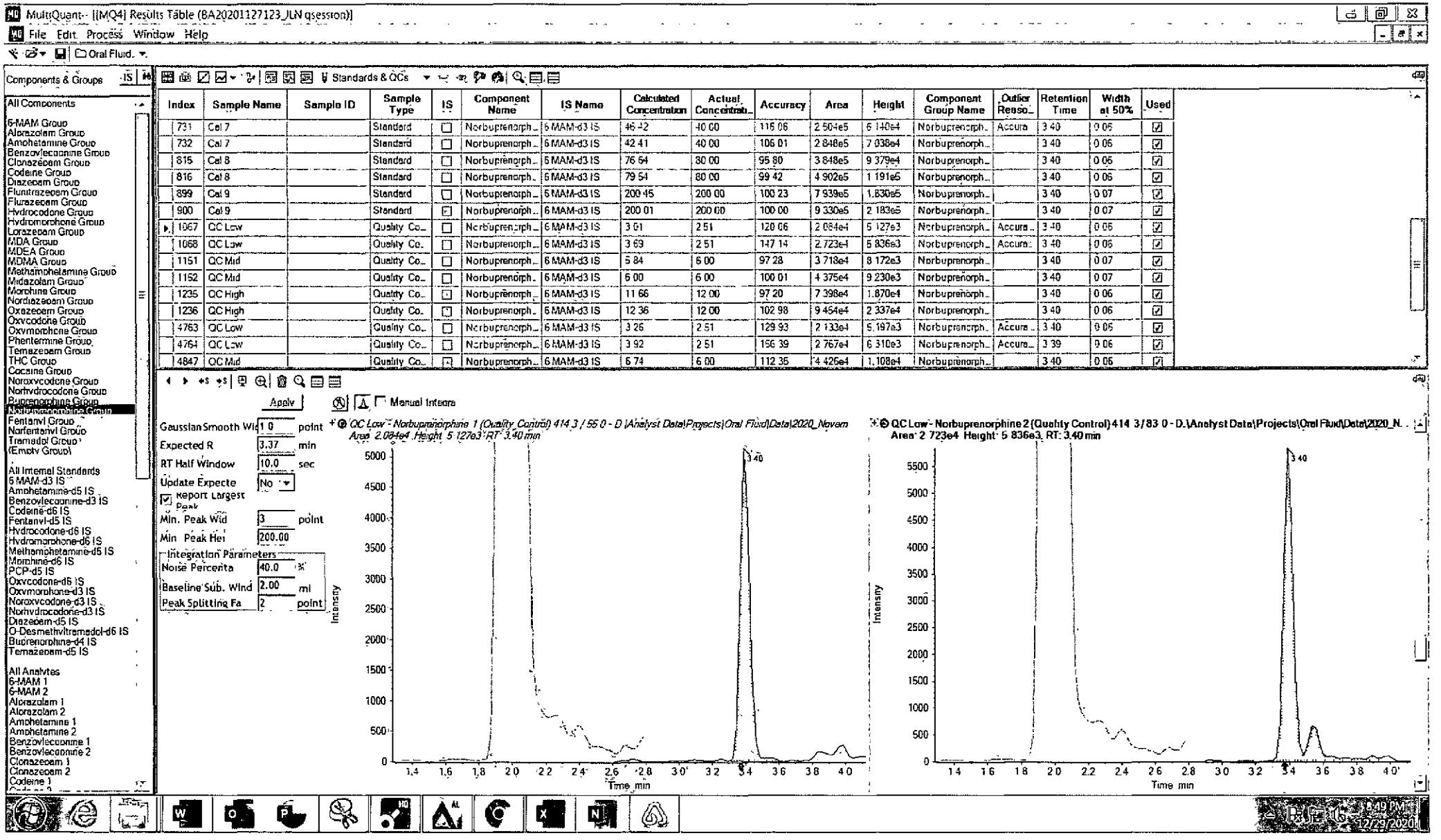
Index	Sample Name	Sample ID	Sample Type	IS	Component Name	IS Name	Component Group Name	Calculated Concentration	Outlier Reaso...	Actual Concentrati...	Area	Height	Retention Time	Width at 50%	Used	Accuracy
1349	12836628-217		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	621.77		N/A	1.047e5	3.240e4	0.91	0.05	☑	N/A
1350	12836628-217		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	492.13		N/A	6.101e5	1.812e5	0.91	0.05	☑	N/A
1422	12877964-215		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1423	12877964-215		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1495	12863451-212		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1496	12863451-212		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1568	12877215-213		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1569	12877215-213		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1641	12871624-212		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1642	12871624-212		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1714	12885750-210		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1715	12885750-210		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1787	12873023-216		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1788	12873023-216		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1860	12899198-216		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1861	12899198-216		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1933	12899057-214		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1934	12899057-214		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A



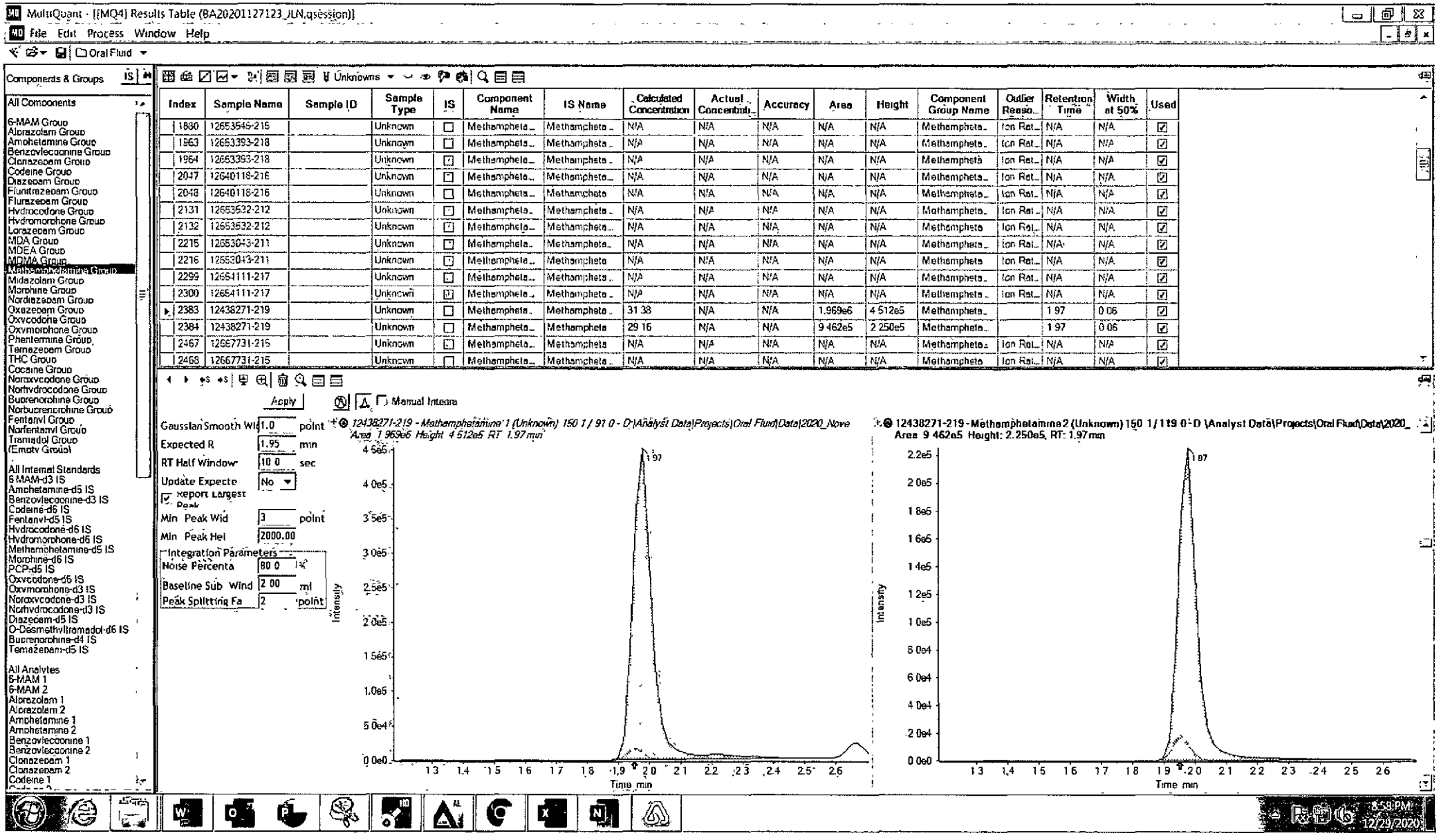
Index	Sample Name	Sample ID	Sample Type	IS	Component Name	IS Name	Component Group Name	Calculated Concentration	Outlier Reason	Actual Concentration	Area	Height	Retention Time	Width at 50%	Used	Accuracy
1276	12873064-210		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1277	12873064-210		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1349	12836628-217		Unknown	■	Morphine 2	Morphine-d6 IS	Morphine	608.41		N/A	1.025e5	3.225e4	0.91	0.05	☑	N/A
1350	12836628-217		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	468.60		N/A	5.820e5	1.806e5	0.91	0.05	☑	N/A
1422	12877964-215		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1423	12877964-215		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1495	12863451-212		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1496	12863451-212		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1568	12877215-213		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1569	12877215-213		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1641	12871624-212		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1642	12871624-212		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1714	12885760-210		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1715	12885760-210		Unknown	☐	Morphine 1	Morphine-d...	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1787	12873023-216		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1788	12873023-216		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1860	12899198-216		Unknown	☐	Morphine 2	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A
1861	12899198-216		Unknown	☐	Morphine 1	Morphine-d6 IS	Morphine	N/A	Ion Rat...	N/A	N/A	N/A	N/A	N/A	☑	N/A

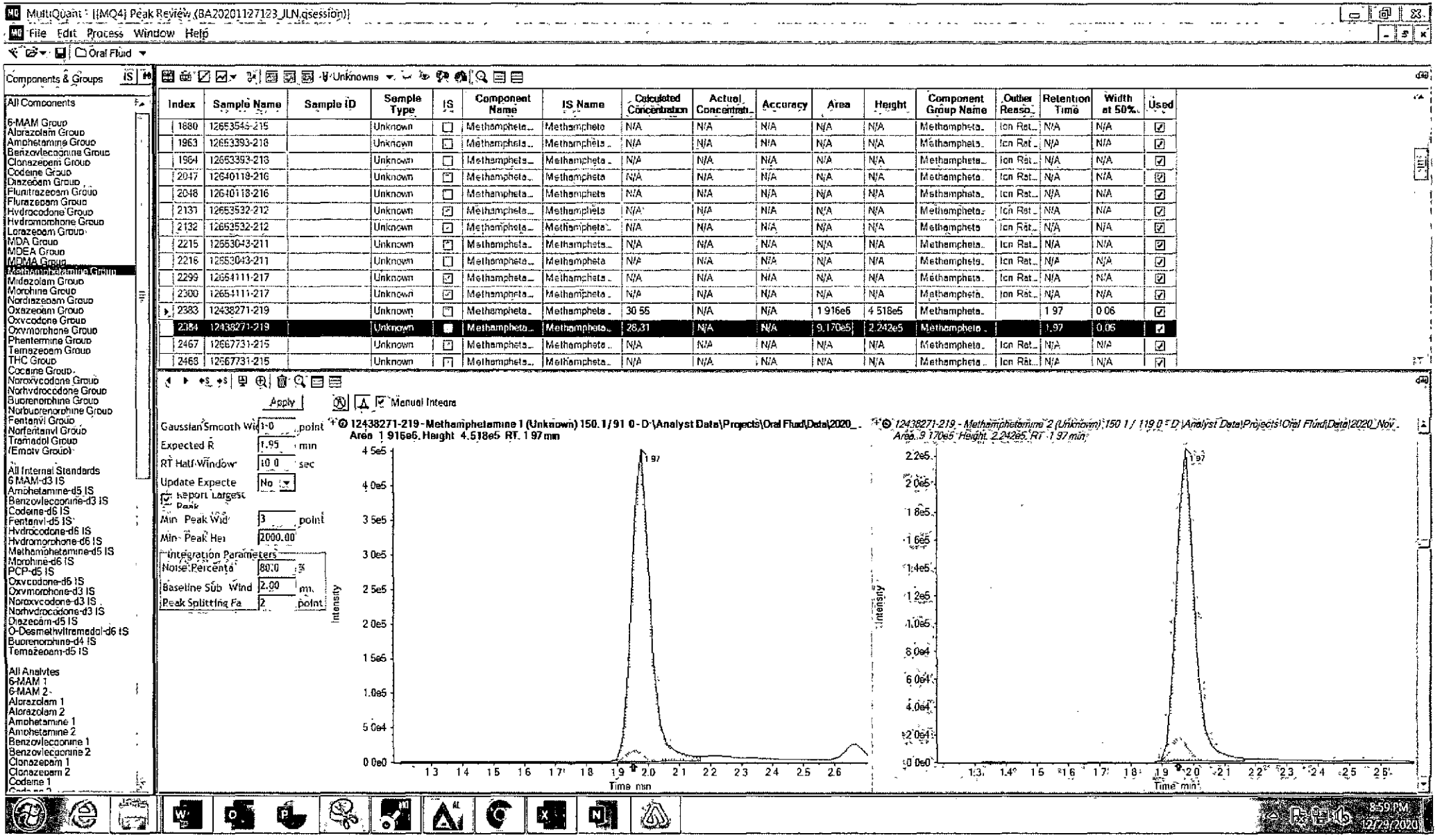


Index	Sample Name	Sample ID	Sample Type	IS	Component Name	IS Name	Component Group Name	Calculated Concentration	Outlier Reaso...	Actual Concentrati...	Area	Height	Retention Time	Width at 50%	Used	Accuracy
1307	12873064-210		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1.00	3 691e5	1 145e5	0 87	0 04		N/A
1388	12836628-217		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	2.689e5	8 794e4	0.89	0 04		N/A
1463	12877964-215		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1.00	2 570e5	7 140e4	0 89	0 05		N/A
1526	12863451-212		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	1 181e5	3 817e4	0 96	0 04		N/A
1699	12877215-213		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	2 053e5	6 111e4	0 90	0 05		N/A
1672	12871624-212		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi	1.00	3 117e5	9 578e4	0 92	0 05		N/A
1745	12885750-210		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	1 852e5	5 327e4	0 90	0 05		N/A
1818	12873023-216		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1.00	3 241e5	1 009e5	0 95	0 05		N/A
1891	12899198-216		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	3 430e5	1 079e5	0 93	0 05		N/A
1964	12899057-214		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi	1 00	2 720e5	8 917e4	0 99	0 04		N/A
2037	12886046-218		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	3 934e5	1 202e5	1 00	0 04		N/A
2110	12899187-219		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	3 509e5	1 019e5	1 04	0 05		N/A
2183	12878396-212		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	3 884e5	1 109e5	1 05	0 05		N/A
2256	12885369-216		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1.00	4 192e5	1 210e5	1 07	0 05		N/A
2329	12899125-210		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi	1 00	3 584e5	9 605e4	1 08	0 05		N/A
2402	12886167-216		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	3 928e5	1 116e5	1.08	0 05		N/A
2475	12899182-210		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1.00	4 143e5	1 285e5	1 07	0.05		N/A
2548	12899138-212		Unknown	☑	Morphine-d6 IS	N/A		N/A	Undefi...	1 00	3 962e5	1 122e5	1.06	0 05		N/A

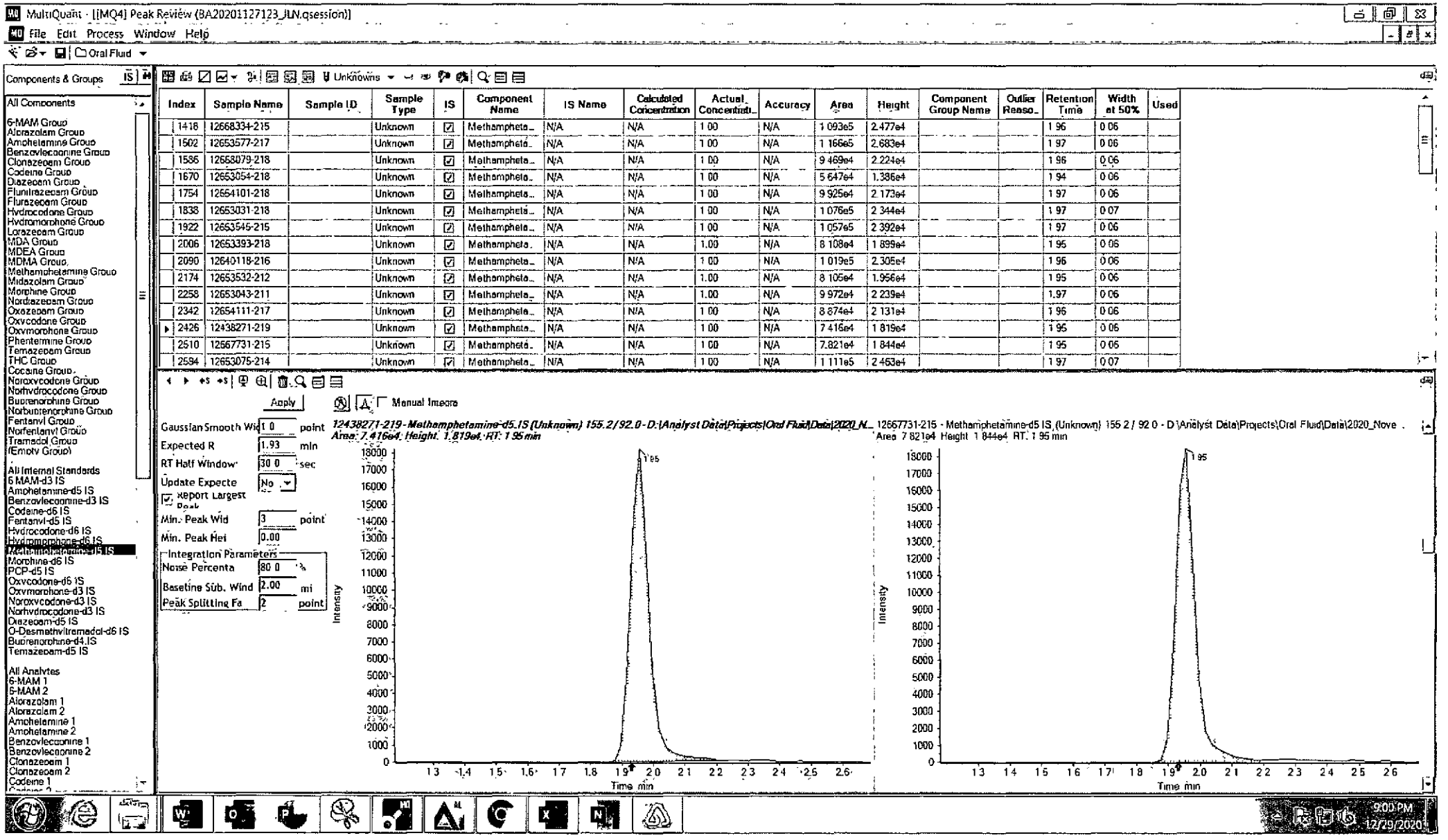


Index	Sample Name	Sample ID	Sample Type	IS	Component Name	IS Name	Calculated Concentration	Actual Concentrati...	Accuracy	Area	Height	Component Group Name	Outlier Reaso...	Retention Time	Width at 50%	Used
731	Cal 7		Standard	☐	Norbuprenorph...	6-MAM-d3 IS	46.42	40.00	116.06	2.504e5	6.140e4	Norbuprenorph...	Accura	3.40	0.06	☑
732	Cal 7		Standard	☐	Norbuprenorph...	6-MAM-d3 IS	42.41	40.00	106.01	2.848e5	7.038e4	Norbuprenorph...		3.40	0.06	☑
815	Cal 8		Standard	☐	Norbuprenorph...	6-MAM-d3 IS	76.64	80.00	95.80	3.848e5	9.379e4	Norbuprenorph...		3.40	0.06	☑
816	Cal 8		Standard	☐	Norbuprenorph...	6-MAM-d3 IS	79.54	80.00	99.42	4.902e5	1.191e5	Norbuprenorph...		3.40	0.06	☑
899	Cal 9		Standard	☐	Norbuprenorph...	6-MAM-d3 IS	200.45	200.00	100.23	7.939e5	1.830e5	Norbuprenorph...		3.40	0.07	☑
900	Cal 9		Standard	☑	Norbuprenorph...	6-MAM-d3 IS	200.01	200.00	100.00	9.330e5	2.183e5	Norbuprenorph...		3.40	0.07	☑
1067	QC Low		Quality Co...	☐	Norbuprenorph...	6-MAM-d3 IS	3.01	2.51	120.06	2.084e4	5.127e3	Norbuprenorph...	Accura...	3.40	0.06	☑
1068	QC Low		Quality Co...	☐	Norbuprenorph...	6-MAM-d3 IS	3.69	2.51	147.14	2.723e4	5.836e3	Norbuprenorph...	Accura...	3.40	0.06	☑
1151	QC Mid		Quality Co...	☐	Norbuprenorph...	6-MAM-d3 IS	5.84	6.00	97.28	3.718e4	8.172e3	Norbuprenorph...		3.40	0.07	☑
1152	QC Mid		Quality Co...	☐	Norbuprenorph...	6-MAM-d3 IS	6.00	6.00	100.01	4.375e4	9.230e3	Norbuprenorph...		3.40	0.07	☑
1235	QC High		Quality Co...	☑	Norbuprenorph...	6-MAM-d3 IS	11.66	12.00	97.20	7.398e4	1.870e4	Norbuprenorph...		3.40	0.06	☑
1236	QC High		Quality Co...	☑	Norbuprenorph...	6-MAM-d3 IS	12.36	12.00	102.98	9.464e4	2.337e4	Norbuprenorph...		3.40	0.06	☑
4763	QC Low		Quality Co...	☐	Norbuprenorph...	6-MAM-d3 IS	3.26	2.51	129.93	2.133e4	5.197e3	Norbuprenorph...	Accura...	3.40	0.06	☑
4764	QC Low		Quality Co...	☐	Norbuprenorph...	6-MAM-d3 IS	3.92	2.51	156.39	2.767e4	6.310e3	Norbuprenorph...	Accura...	3.39	0.06	☑
4847	QC Mid		Quality Co...	☑	Norbuprenorph...	6-MAM-d3 IS	6.74	6.00	112.35	4.426e4	1.108e4	Norbuprenorph...		3.40	0.06	☑


MultiQuant - [[MQ4] Results Table (BA20201127123_JLN.qsession)]
File Edit Process Window Help
Oral Fluid
Components & Groups
All Components
Unknowns
Index | Sample Name | Sample ID | Sample Type | IS | Component Name | IS Name | Calculated Concentration | Actual Concentration | Accuracy | Area | Height | Component Group Name | Outlier Reason | Retention Time | Width at 50% | Used
1880 | 12653545-215 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
1963 | 12653393-218 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
1964 | 12653393-218 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2047 | 12640118-216 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2048 | 12640118-216 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2131 | 12653532-212 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2132 | 12653532-212 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2215 | 12653043-211 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2216 | 12653043-211 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2299 | 12654111-217 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2300 | 12654111-217 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2383 | 12438271-219 | Unknown | Methamphetamine | Methamphetamine | 31.38 | N/A | N/A | 1.969e6 | 4.512e5 | Methamphetamine | | 1.97 | 0.06
2384 | 12438271-219 | Unknown | Methamphetamine | Methamphetamine | 29.16 | N/A | N/A | 9.462e5 | 2.250e5 | Methamphetamine | | 1.97 | 0.06
2467 | 12667731-215 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
2468 | 12667731-215 | Unknown | Methamphetamine | Methamphetamine | N/A | N/A | N/A | N/A | N/A | Methamphetamine | Ion Ratio | N/A | N/A
Apply
Manual Integra
Gaussian Smooth Wid 1.0 point
Expected R 1.95 min
RT Half Window 10.0 sec
Update Expecte No
Report Largest Peak
Min Peak Wid 3 point
Min Peak Hei 2000.00
Integration Parameters
Noise Percenta 80.0
Baseline Sub Wind 2.00 ml
Peak Splitting Fa 2 point
12438271-219 - Methamphetamine 1 (Unknown) 150 1 / 91 0 - D:\Analyst Data\Projects\Oral Fluid\Data\2020_Nove
Area: 1.969e6 Height: 4.512e5 RT: 1.97 min
Intensity
Time_min
12438271-219 - Methamphetamine 2 (Unknown) 150 1 / 119 0 - D:\Analyst Data\Projects\Oral Fluid\Data\2020_
Area: 9.462e5 Height: 2.250e5, RT: 1.97 min
Intensity
Time_min
All Internal Standards
6-MAM-d3 IS
Amphetamine-d5 IS
Benzoylecgonine-d3 IS
Codeine-d6 IS
Fentanyl-d5 IS
Hydrocodone-d6 IS
Hydromorphone-d6 IS
Methamphetamine-d5 IS
Morphine-d6 IS
PCP-d5 IS
Oxycodone-d6 IS
Oxymorphone-d3 IS
Noroxycodone-d3 IS
Norhydrocodone-d3 IS
Diazepam-d5 IS
O-Desmethyltramadol-d6 IS
Buprenorphine-d4 IS
Temazepam-d5 IS
All Analytes
6-MAM 1
6-MAM 2
Alprazolam 1
Alprazolam 2
Amphetamine 1
Amphetamine 2
Benzoylecgonine 1
Benzoylecgonine 2
Clonazepam 1
Clonazepam 2
Codeine 1
8:58 PM
12/29/2020

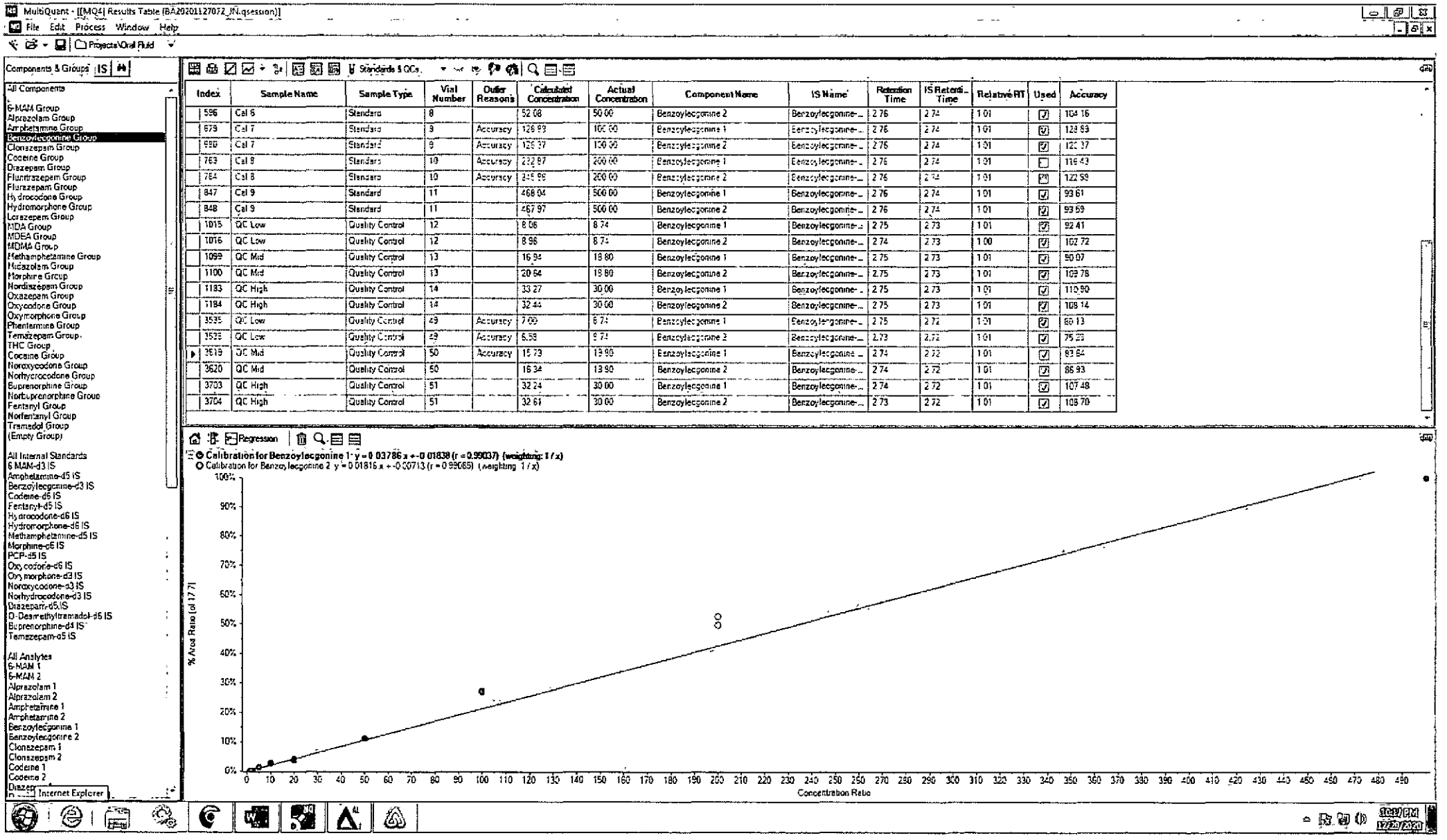


Index	Sample Name	Sample ID	Sample Type	IS	Component Name	IS Name	Calculated Concentration	Actual Concentrati...	Accuracy	Area	Height	Component Group Name	Outlier Reaso...	Retention Time	Width at 50%	Used
1880	12653546-215		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
1963	12653393-218		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
1964	12653393-218		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2047	12640118-216		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2048	12640118-216		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2131	12653532-212		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2132	12653532-212		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2215	12653043-211		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2216	12653043-211		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2299	12654111-217		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2300	12654111-217		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2383	12438271-219		Unknown		Methampheta...	Methampheta...	30.55		N/A	1.916e6	4.518e5	Methampheta...		1.97	0.06	
2384	12438271-219		Unknown		Methampheta...	Methampheta...	28.31		N/A	9.170e5	2.242e5	Methampheta...		1.97	0.06	
2467	12667731-215		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	
2468	12667731-215		Unknown		Methampheta...	Methampheta...	N/A		N/A	N/A	N/A	Methampheta...	Ion Rat...	N/A	N/A	

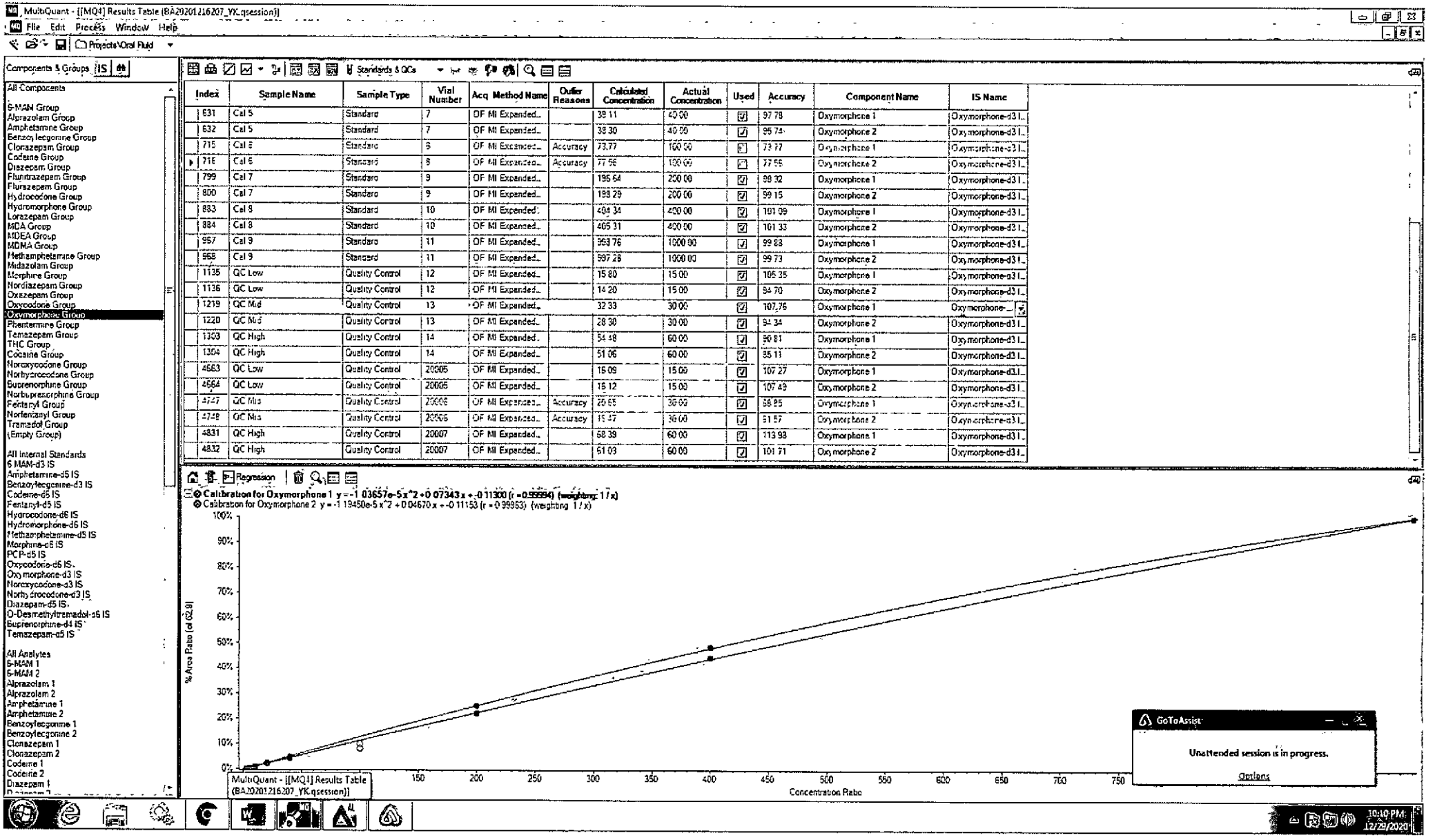


Index	Sample Name	Sample ID	Sample Type	IS	Component Name	IS Name	Calculated Concentration	Actual Concentrati...	Accuracy	Area	Height	Component Group Name	Outlier Reaso...	Retention Time	Width at 50%	Used
1418	12668334-215		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	1.093e5	2.477e4			1.96	0.06	
1502	12653577-217		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	1.166e5	2.683e4			1.97	0.06	
1586	12668079-218		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	9.469e4	2.224e4			1.96	0.06	
1670	12653054-218		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	5.647e4	1.386e4			1.94	0.06	
1754	12664101-218		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	9.925e4	2.173e4			1.97	0.06	
1838	12653031-218		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	1.076e5	2.344e4			1.97	0.07	
1922	12653545-215		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	1.057e5	2.392e4			1.97	0.06	
2006	12653393-218		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	8.108e4	1.899e4			1.95	0.06	
2090	12640118-216		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	1.019e5	2.305e4			1.96	0.06	
2174	12653532-212		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	8.105e4	1.956e4			1.95	0.06	
2258	12653043-211		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	9.972e4	2.239e4			1.97	0.06	
2342	12654111-217		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	8.874e4	2.131e4			1.96	0.06	
2426	12438271-219		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	7.416e4	1.819e4			1.95	0.06	
2510	12667731-215		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	7.821e4	1.844e4			1.95	0.06	
2594	12653075-214		Unknown	☑	Methampheta...	N/A	N/A	1.00	N/A	1.111e5	2.453e4			1.97	0.07	

Attachment E12 to E14, Calibration Curve with Points Excluded



Index	Sample Name	Sample Type	Vial Number	Outlier Reasons	Calculated Concentration	Actual Concentration	Component Name	IS Name	Retention Time	IS Retenti... Time	Relative RT	Used	Accuracy
596	Cal 6	Standard	8		52.08	50.00	Benzoylecgonine 2	Benzoylecgonine-...	2.76	2.74	1.01	☑	104.16
679	Cal 7	Standard	9	Accuracy	126.93	100.00	Benzoylecgonine 1	Benzoylecgonine-...	2.76	2.74	1.01	☑	126.93
680	Cal 7	Standard	9	Accuracy	126.97	100.00	Benzoylecgonine 2	Benzoylecgonine-...	2.76	2.74	1.01	☑	126.97
763	Cal 8	Standard	10	Accuracy	232.87	200.00	Benzoylecgonine 1	Benzoylecgonine-...	2.76	2.74	1.01	☐	116.43
764	Cal 8	Standard	10	Accuracy	245.99	200.00	Benzoylecgonine 2	Benzoylecgonine-...	2.76	2.74	1.01	☑	122.99
847	Cal 9	Standard	11		468.04	500.00	Benzoylecgonine 1	Benzoylecgonine-...	2.76	2.74	1.01	☑	93.61
848	Cal 9	Standard	11		467.97	500.00	Benzoylecgonine 2	Benzoylecgonine-...	2.76	2.74	1.01	☑	93.59
1015	QC Low	Quality Control	12		8.06	8.74	Benzoylecgonine 1	Benzoylecgonine-...	2.75	2.73	1.01	☑	92.41
1016	QC Low	Quality Control	12		8.96	8.74	Benzoylecgonine 2	Benzoylecgonine-...	2.74	2.73	1.00	☑	102.72
1099	QC Mid	Quality Control	13		16.94	18.80	Benzoylecgonine 1	Benzoylecgonine-...	2.75	2.73	1.01	☑	90.07
1100	QC Mid	Quality Control	13		20.64	18.80	Benzoylecgonine 2	Benzoylecgonine-...	2.75	2.73	1.01	☑	109.78
1183	QC High	Quality Control	14		33.27	30.00	Benzoylecgonine 1	Benzoylecgonine-...	2.75	2.73	1.01	☑	110.90
1184	QC High	Quality Control	14		32.44	30.00	Benzoylecgonine 2	Benzoylecgonine-...	2.75	2.73	1.01	☑	108.14
3535	QC Low	Quality Control	49	Accuracy	7.69	8.74	Benzoylecgonine 1	Benzoylecgonine-...	2.75	2.72	1.01	☑	88.13
3536	QC Low	Quality Control	49	Accuracy	6.58	8.74	Benzoylecgonine 2	Benzoylecgonine-...	2.73	2.72	1.01	☑	75.28
3619	QC Mid	Quality Control	50	Accuracy	15.73	18.80	Benzoylecgonine 1	Benzoylecgonine-...	2.74	2.72	1.01	☑	83.64
3620	QC Mid	Quality Control	50		16.34	18.80	Benzoylecgonine 2	Benzoylecgonine-...	2.74	2.72	1.01	☑	86.93
3703	QC High	Quality Control	51		32.24	30.00	Benzoylecgonine 1	Benzoylecgonine-...	2.74	2.72	1.01	☑	107.48
3704	QC High	Quality Control	51		32.61	30.00	Benzoylecgonine 2	Benzoylecgonine-...	2.73	2.72	1.01	☑	108.70



Index	Sample Name	Sample Type	Vial Number	Acq Method Name	Outlier Reasons	Calculated Concentration	Actual Concentration	Used	Accuracy	Component Name	IS Name
631	Cal 5	Standard	7	OF MI Expanded...		39.11	40.00	☑	97.78	Oxymorphone 1	Oxymorphone-d3 I...
632	Cal 5	Standard	7	OF MI Expanded...		38.30	40.00	☑	95.74	Oxymorphone 2	Oxymorphone-d3 I...
715	Cal 6	Standard	8	OF MI Expanded...	Accuracy	73.77	100.00	☐	73.77	Oxymorphone 1	Oxymorphone-d3 I...
716	Cal 6	Standard	8	OF MI Expanded...	Accuracy	77.56	100.00	☐	77.56	Oxymorphone 2	Oxymorphone-d3 I...
799	Cal 7	Standard	9	OF MI Expanded...		196.64	200.00	☑	98.32	Oxymorphone 1	Oxymorphone-d3 I...
800	Cal 7	Standard	9	OF MI Expanded...		198.29	200.00	☑	99.15	Oxymorphone 2	Oxymorphone-d3 I...
883	Cal 8	Standard	10	OF MI Expanded...		404.34	400.00	☑	101.09	Oxymorphone 1	Oxymorphone-d3 I...
884	Cal 8	Standard	10	OF MI Expanded...		405.31	400.00	☑	101.33	Oxymorphone 2	Oxymorphone-d3 I...
967	Cal 9	Standard	11	OF MI Expanded...		998.76	1000.00	☑	99.88	Oxymorphone 1	Oxymorphone-d3 I...
968	Cal 9	Standard	11	OF MI Expanded...		997.28	1000.00	☑	99.73	Oxymorphone 2	Oxymorphone-d3 I...
1135	QC Low	Quality Control	12	OF MI Expanded...		15.80	15.00	☑	105.35	Oxymorphone 1	Oxymorphone-d3 I...
1136	QC Low	Quality Control	12	OF MI Expanded...		14.20	15.00	☑	94.70	Oxymorphone 2	Oxymorphone-d3 I...
1219	QC Mid	Quality Control	13	OF MI Expanded...		32.33	30.00	☑	107.76	Oxymorphone 1	Oxymorphone-...
1220	QC Mid	Quality Control	13	OF MI Expanded...		28.30	30.00	☑	94.34	Oxymorphone 2	Oxymorphone-d3 I...
1303	QC High	Quality Control	14	OF MI Expanded...		54.48	60.00	☑	90.81	Oxymorphone 1	Oxymorphone-d3 I...
1304	QC High	Quality Control	14	OF MI Expanded...		51.06	60.00	☑	85.11	Oxymorphone 2	Oxymorphone-d3 I...
4663	QC Low	Quality Control	20005	OF MI Expanded...		16.09	15.00	☑	107.27	Oxymorphone 1	Oxymorphone-d3 I...
4664	QC Low	Quality Control	20005	OF MI Expanded...		16.12	15.00	☑	107.49	Oxymorphone 2	Oxymorphone-d3 I...
4747	QC Mid	Quality Control	20006	OF MI Expanded...	Accuracy	26.65	30.00	☑	88.85	Oxymorphone 1	Oxymorphone-d3 I...
4748	QC Mid	Quality Control	20006	OF MI Expanded...	Accuracy	15.47	30.00	☑	51.57	Oxymorphone 2	Oxymorphone-d3 I...
4831	QC High	Quality Control	20007	OF MI Expanded...		68.39	60.00	☑	113.98	Oxymorphone 1	Oxymorphone-d3 I...
4832	QC High	Quality Control	20007	OF MI Expanded...		61.03	60.00	☑	101.71	Oxymorphone 2	Oxymorphone-d3 I...

MultiQuant - [[MQ4] Results Table (BA20201130136_MRM qsession)]

File Edit Process Window Help

Projects\Oral Fluid

Components & Groups | IS

All Components
6-MAM Group
Alprazolam Group
Amphetamine Group
Benzoylecgonine Group
Clonazepam Group
Codeine Group
Diazepam Group
Flunitrazepam Group
Flurazepam Group
Hydrocodone Group
Hydromorphone Group
Lorazepam Group
MDA Group
MDEA Group
MDMA Group
Methamphetamine Group
Midazolam Group
Morphine Group
Nordiazepam Group
Oxazepam Group
Oxycodone Group
Oxymorphone Group
Phentermine Group
Temazepam Group
THC Group
Cocaine Group
Noroxycodone Group
Norhydrocodone Group
Buprenorphine Group
Norbuprenorphine Group
Fentanyl Group
Norfentanyl Group
Tramadol Group
(Empty Group)

All Internal Standards
6 MAM-d3 IS
Amphetamine-d5 IS
Benzoylecgonine-d3 IS
Codeine-d6 IS
Fentanyl-d5 IS
Hydrocodone-d6 IS
Hydromorphone-d6 IS
Methamphetamine-d5 IS
Morphine-d6 IS
PCP-d5 IS
Oxycodone-d6 IS
Oxymorphone-d3 IS
Noroxycodone-d3 IS
Norhydrocodone-d3 IS
Diazepam-d5 IS
O-Desmethyltramadol-d6 IS
Buprenorphine-d4 IS
Temazepam-d5 IS

All Analytes
6-MAM 1
6-MAM 2
Alprazolam 1
Alprazolam 2
Amphetamine 1
Amphetamine 2
Benzoylecgonine 1
Benzoylecgonine 2
Clonazepam 1
Clonazepam 2
Codeine 1
Codeine 2
Diazep...

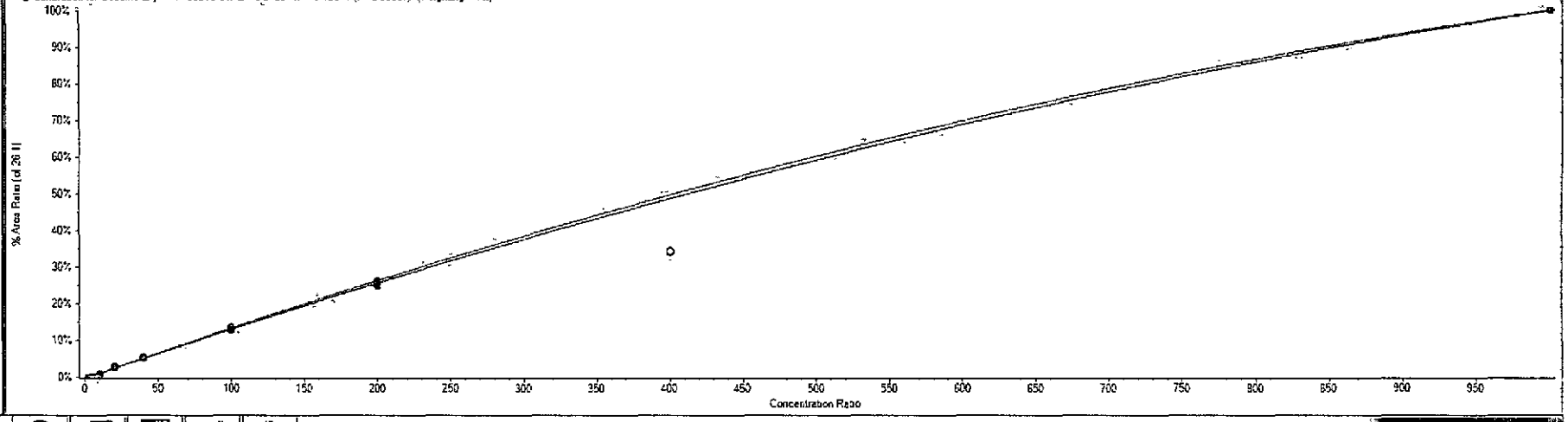
Internet Explorer

Standards & QCs

Index	Sample Name	Sample Type	Vial Number	Component Name	IS Name	Outlier Reasons	Calculated Concentration	Actual Concentration	Accuracy	Retention Time	Relative RT	IS Retenti... Time	IS Area	Used
600	Cal 6	Standard	51	Codeine 2	Codeine-d6 IS		100 82	100 00	100 82	1 64	1 02	1 61	23152	☑
683	Cal 7	Standard	52	Codeine 1	Codeine-d6 IS		194 17	200 00	97 09	1 64	1 02	1 61	19612	☑
684	Cal 7	Standard	52	Codeine 2	Codeine-d6 IS		198 70	200 00	99 35	1 64	1 02	1 61	19612	☑
767	Cal 8	Standard	53	Codeine 1	Codeine-d6 IS	Accuracy	273 07	400 00	68 27	1 65	1 02	1 61	25303	☐
768	Cal 8	Standard	53	Codeine 2	Codeine-d6 IS	Accuracy	253 09	400 00	55 77	1 64	1 02	1 61	25303	☐
851	Cal 9	Standard	54	Codeine 1	Codeine-d6 IS		1002 02	1000 00	100 20	1 64	1 02	1 61	18589	☑
852	Cal 9	Standard	54	Codeine 2	Codeine-d6 IS		1000 33	1000 00	100 03	1 64	1 02	1 61	18589	☑
1019	QC Low	Quality Control	55	Codeine 1	Codeine-d6 IS		13 43	12 37	108 59	1 63	1 02	1 60	25080	☑
1020	QC Low	Quality Control	55	Codeine 2	Codeine-d6 IS		14 05	12 37	113 60	1 63	1 02	1 60	25080	☑
1103	QC Mid	Quality Control	56	Codeine 1	Codeine-d6 IS		29 76	30 00	99 20	1 63	1 02	1 60	34005	☑
1104	QC Mid	Quality Control	56	Codeine 2	Codeine-d6 IS		30 19	30 00	100 65	1 64	1 02	1 60	34005	☑
1187	QC High	Quality Control	57	Codeine 1	Codeine-d6 IS	Accuracy	45 25	60 00	75 41	1 63	1 02	1 60	38429	☑
1188	QC High	Quality Control	57	Codeine 2	Codeine-d6 IS	Accuracy	46 97	60 00	78 28	1 63	1 02	1 60	38429	☑
4715	QC LOW	Quality Control	98	Codeine 1	Codeine-d6 IS		12 88	12 37	104 09	1 62	1 02	1 60	32967	☑
4716	QC LOW	Quality Control	98	Codeine 2	Codeine-d6 IS		13 41	12 37	108 43	1 63	1 02	1 60	32967	☑
4799	QC MID	Quality Control	99	Codeine 1	Codeine-d6 IS		29 78	30 00	99 25	1 63	1 02	1 60	32313	☑
4800	QC MID	Quality Control	99	Codeine 2	Codeine-d6 IS		26 98	30 00	89 94	1 62	1 01	1 60	32313	☑
4883	QC HIGH	Quality Control	100	Codeine 1	Codeine-d6 IS		54 09	60 00	90 16	1 64	1 02	1 61	33220	☑
4884	QC HIGH	Quality Control	100	Codeine 2	Codeine-d6 IS		52 99	60 00	88 31	1 64	1 02	1 61	33220	☑

Regression

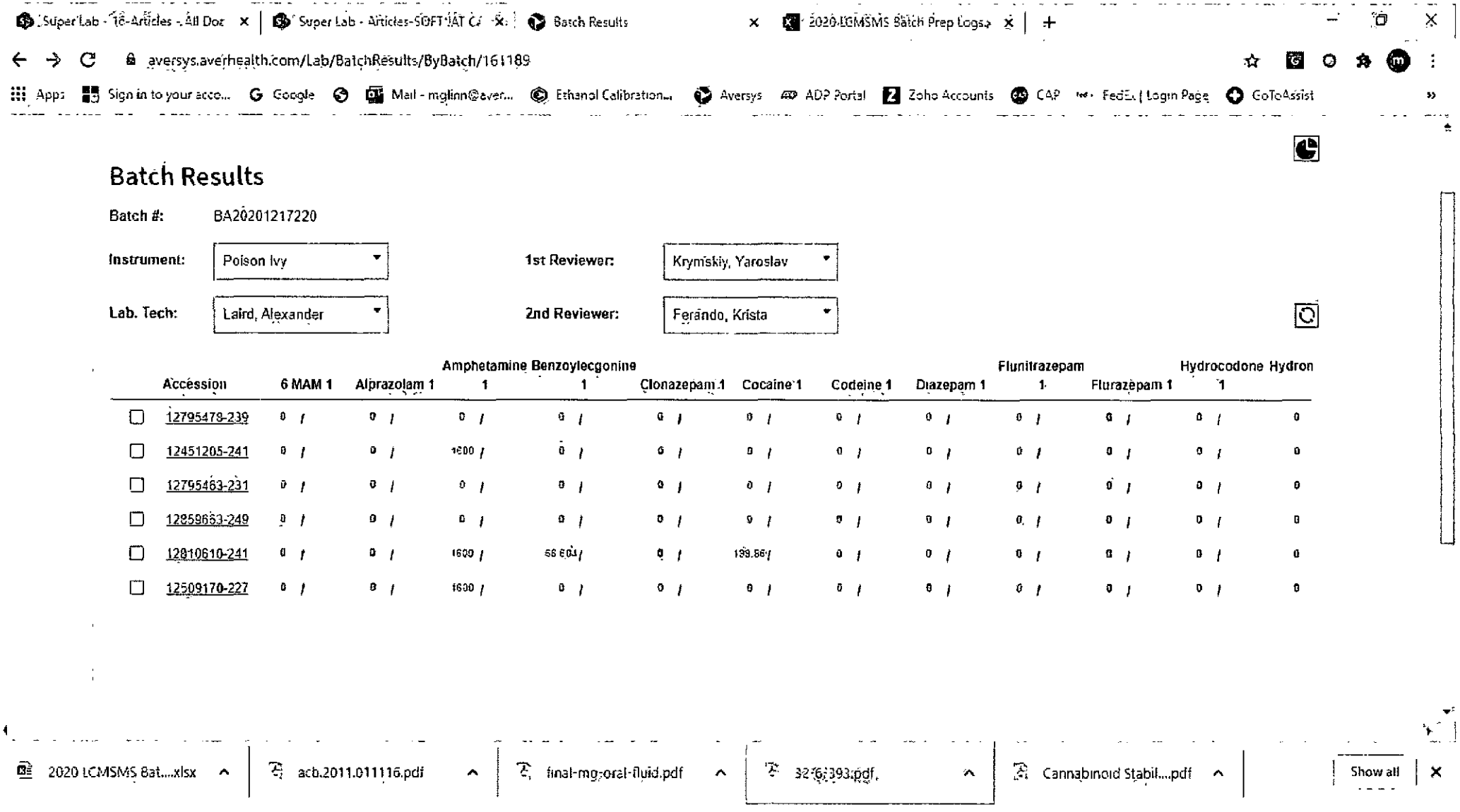
Calibration for Codeine 1: y = -9.87130e-6 x^2 + 0.03600 x + -0.08289 (r = 0.99889) (weighting: 1 / x)
Calibration for Codeine 2: y = -1.48851e-5 x^2 + 0.04894 x + -0.12371 (r = 0.99967) (weighting: 1 / x)



10:20 PM
12/29/2020

Attachment E16, Sample Review Log

DATE	Batch Number	Instrument	Method	Number of samples	Aliquot Samples into microtiger tubes	Sample Prep morning/Ultrasy/ evening	Sample Transfer to Vials	Vial Sequence Set	Double Check Sequence	Submit Batch	Sample Sequence and remove autosamp
01/02/20	BA20200102065	LCMS_VM	MI OF	40	KW	01/02/20	KW	01/02/20	KW	01/02/20	KW
01/02/20	BA20200102033	LCMS_DS	MI OF	40	KW	01/02/20	KW	01/02/20	KW	01/02/20	PB
01/02/20	BA20191231097	LCMS_FS	Syn Stim	34	MS	12/31/19	MS	12/31/19	PB	01/02/20	KM
01/02/19	BA20200102122	LCMS_LS	MI OF	38	KW	01/02/20	KW	01/02/20	KW	01/02/20	KW
01/02/20	BA20200102110	LCMS_LS	MI OF	39	AS	01/02/20	AS	01/02/20	KW	01/02/20	KW
01/02/20	BA20200102010	LCMS_FL	Specialty	9	KM	01/02/20	KM	01/02/20	JNC	01/02/20	PB
01/02/20	BA20200101005	LCMS_SM	THC	122	JC	01/02/20	JC	01/02/20	JC/AL	01/02/20	AL/KW
01/02/20	BA20200102011_p11	LCMS_RD	Standard	133	JC/KM/MS	01/02/20	JYC	01/02/20	JYC/AM	01/02/20	JYC/PB
01/02/20	BA20200102004	LCMS_FL	Analgesic	28	KM	01/02/20	KM	01/02/20	PB	01/02/20	KM
01/02/20	BA20191231242	LCMS_PI	HAIR	67	MH	12/31/19	CC	01/02/20	CC	01/02/20	KW
01/02/20	BA20200102154	GCMS_PG	ETOH	16	AM	01/02/19	AM	01/02/20	AM	01/02/20	
01/02/20	BA20200102011_p12	LCMS_FL	Standard		JC/KM/MS	01/02/20	JYC	01/02/20	JNC/KM	01/02/20	JYC
01/02/20	BA20200102136	LCMS_LX	MI OF	11	AL	01/02/20	AM	01/02/20	AM	01/02/20	AM
01/02/20	BA20200102142	LCMS_LX	OF ABBV	20	AL	01/02/20	AL	01/02/20	AM	01/02/20	AM
01/02/20	BA20200102113	LCMS_VM	MI OF	42	AL	01/02/20	AL	01/02/20	AL	01/02/20	KW
01/02/20	BA20200102006	LCMS_FS	KRATOM	9	MS	01/02/20	MS	01/02/20	KM	01/03/20	JNC
01/03/19	BA20191231203_reinjects	LCMS_LX	MI OF	3	JNC	01/03/20	JNC	01/03/20	JNC	01/03/20	
01/03/20	BA20200103118	LCMS_DS	MI OF	40	AL	01/03/19	AL	01/03/19	AL	01/03/19	AH
01/03/20	BA20200103137	LCMS_LX	MI OF	38	AM	01/03/19	AM	01/03/19	AM	01/03/19	AH
01/03/20	BA20200103156	LCMS_LS	MI OF	37	AL	01/03/19	AL	01/03/19	AL	01/03/19	AL
01/03/20	BA20200103131	LCMS_VM	MI OF	40	AS	01/03/20	AS	01/03/20	AS	01/03/20	AS
01/03/20	BA20200103041	LCMS_BN	MI OF	40	KW	01/03/20	KW	01/03/20	KW	01/03/20	KW
01/03/20	BA20200103183	LCMS_LS	MI OF	39	AS	01/03/20	AS	01/03/20	AS	01/03/20	AL
01/03/20	BA20200103206	LCMS_BN	MI OF	40	KW	01/03/20	KW	01/03/20	KW	01/03/20	AH
01/03/20	BA20200103014	LCMS_SM	THC	123	JC	01/03/20	JC	01/03/20	AM/AL	01/03/20	AL/AH
01/03/20	BA20200102013	LCMS_FS	ETG	72	KM	01/02/20	MS	01/02/20	JNC	01/03/20	AH
01/03/20	BA20200103035	LCMS_RD	Standard	136	KM/JC	01/03/20	JYC	01/03/20	JYC	01/03/20	JYC
01/03/20	BA20200103144	LCMS_DS	MI OF	40	AM	01/03/20	AM	01/03/20	AM	01/03/20	AM
01/03/20	BA20200103232	LCMS_VM	MI OF	32	AS	01/30/20	AS	01/30/20	AS	01/30/20	AL
01/03/20	BA20200103187	LCMS_LX	MI OF	37	AL	01/03/19	AL	01/03/19	AL	01/03/19	AH
01/03/20	BA20200103064	LCMS_FL	Standard	41	MS	01/03/20	JYC	01/03/20	JYC	01/03/20	AH
01/03/20	BA20200103013	LCMS_FL	Analgesic	31	JC/MS	01/03/20	MS	01/03/20	MS	01/03/20	AH/?
01/03/20	BA20200102148	LCMS_PI	HAIR	69	CC	01/02/20	CC	01/03/20	CC	01/03/20	?
01/04/20	BA20200103022	LCMS_FS	ETG	81	KM	01/03/20	KM	01/03/20	AH	01/04/20	AH
01/04/20	BA20200102148	LCMS_FL	Specialty	4	KM	01/02/20	KM	01/02/20	AH	01/04/20	?


Super Lab - 16-Articles - All Doc
Super Lab - Articles-SOFTJAT C
Batch Results
2020 LCMSMS Batch Prep Logs
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Apps
Sign in to your acco...
Google
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Ethanol Calibration...
Aversys
ADP Portal
Zoho Accounts
CAP
FedEx Login Page
GoToAssist
Batch Results
Batch #: BA20201217220
Instrument: Poison Ivy
1st Reviewer: Krymskiy, Yaroslav
Lab. Tech: Laird, Alexander
2nd Reviewer: Ferando, Krista
Accession
6 MAM 1
Alprazolam 1
Amphetamine 1
Benzoylecgonine 1
Clonazepam 1
Cocaine 1
Codeine 1
Diazepam 1
Flunitrazepam 1
Flurazepam 1
Hydrocodone 1
Hydron
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12451205-241
12795463-231
12859683-249
12810610-241
12509170-227
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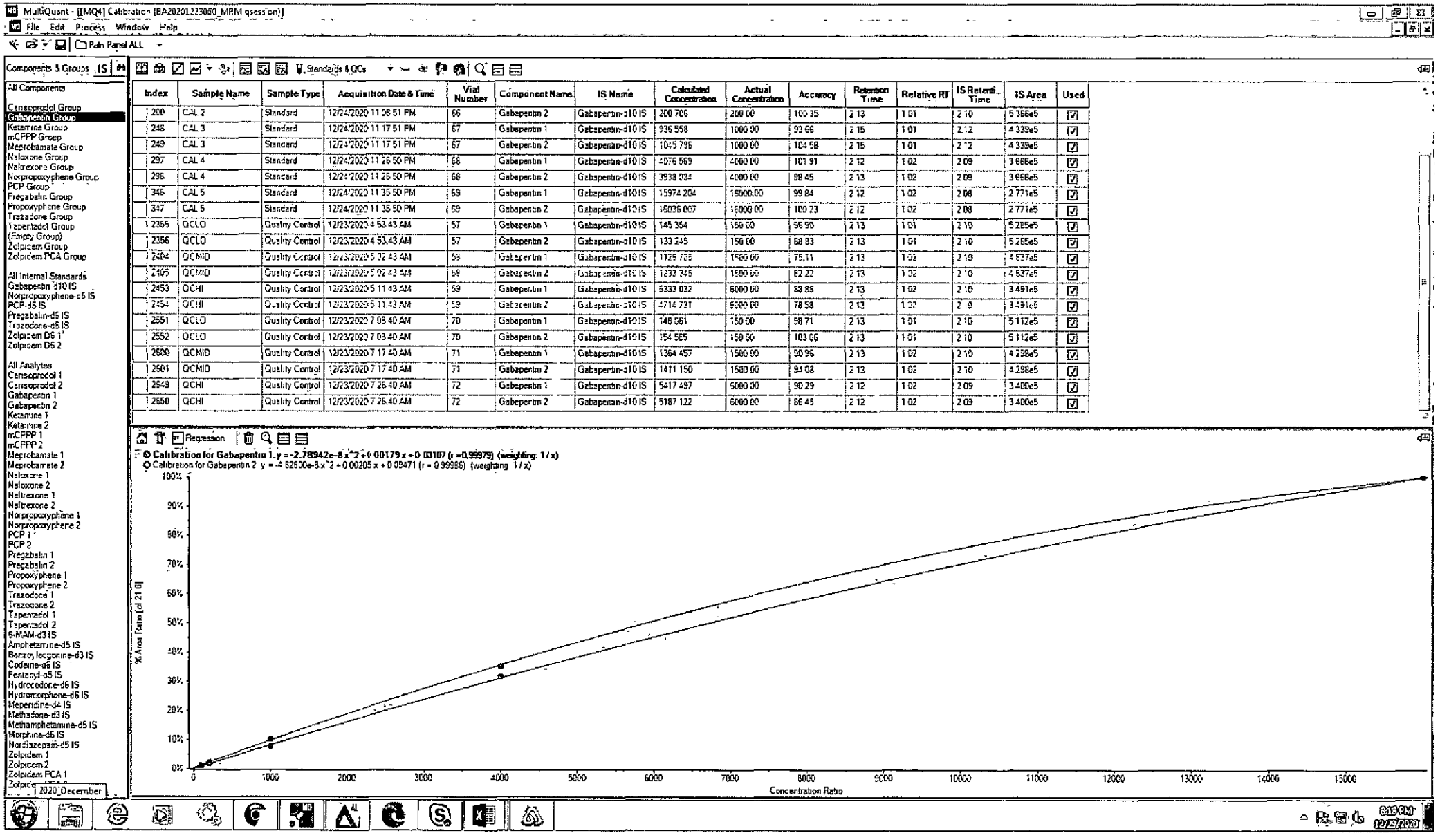
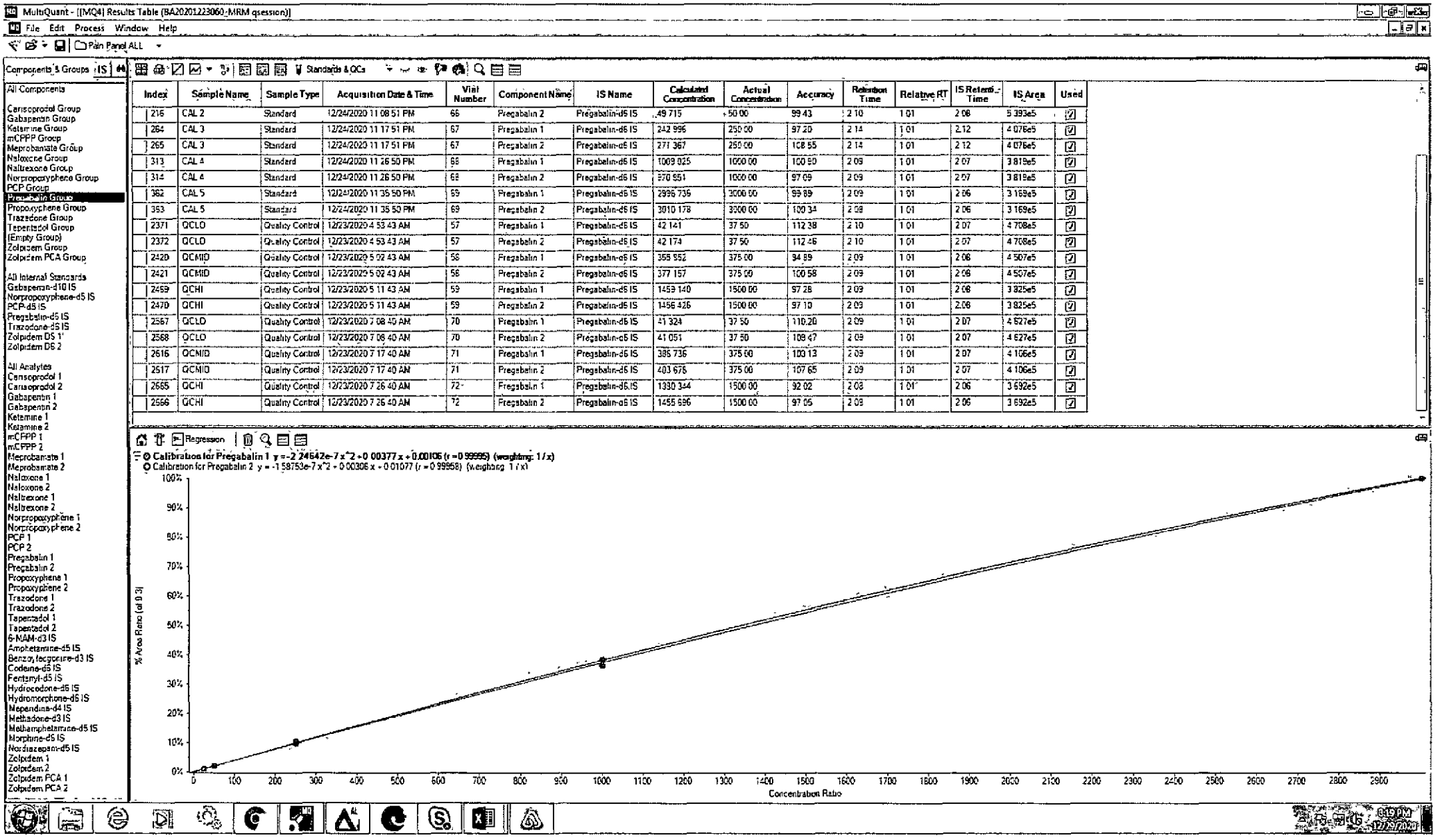
3276393.pdf
Cannabinoid Stabil....pdf
Show all

F1 to F2, Historical Quality Control Used



Index	Sample Name	Sample Type	Acquisition Date & Time	Vial Number	Component Name	IS Name	Calculated Concentration	Actual Concentration	Accuracy	Retention Time	Relative RT	IS Retenti... Time	IS Area	Used
200	CAL 2	Standard	12/24/2020 11 08 51 PM	66	Gabapentin 2	Gabapentin-d10 IS	200 706	200 00	100 35	2 13	1 01	2 10	5 358e5	☑
248	CAL 3	Standard	12/24/2020 11 17 51 PM	67	Gabapentin 1	Gabapentin-d10 IS	936 558	1000 00	93 66	2 15	1 01	2 12	4 339e5	☑
249	CAL 3	Standard	12/24/2020 11 17 51 PM	67	Gabapentin 2	Gabapentin-d10 IS	1045 795	1000 00	104 58	2 15	1 01	2 12	4 339e5	☑
297	CAL 4	Standard	12/24/2020 11 26 50 PM	68	Gabapentin 1	Gabapentin-d10 IS	4076 569	4000 00	101 91	2 12	1 02	2 09	3 666e5	☑
298	CAL 4	Standard	12/24/2020 11 26 50 PM	68	Gabapentin 2	Gabapentin-d10 IS	3938 034	4000 00	98 45	2 13	1 02	2 09	3 666e5	☑
346	CAL 5	Standard	12/24/2020 11 35 50 PM	69	Gabapentin 1	Gabapentin-d10 IS	15974 204	16000 00	99 84	2 12	1 02	2 08	2 771e5	☑
347	CAL 5	Standard	12/24/2020 11 35 50 PM	69	Gabapentin 2	Gabapentin-d10 IS	16036 007	16000 00	100 23	2 12	1 02	2 08	2 771e5	☑
2355	QCLO	Quality Control	12/23/2020 4 53 43 AM	57	Gabapentin 1	Gabapentin-d10 IS	145 364	150 00	96 90	2 13	1 01	2 10	5 285e5	☑
2356	QCLO	Quality Control	12/23/2020 4 53 43 AM	57	Gabapentin 2	Gabapentin-d10 IS	133 245	150 00	88 83	2 13	1 01	2 10	5 285e5	☑
2404	QCMID	Quality Control	12/23/2020 5 02 43 AM	58	Gabapentin 1	Gabapentin-d10 IS	1126 735	1500 00	75 11	2 13	1 02	2 10	4 637e5	☑
2405	QCMID	Quality Control	12/23/2020 5 02 43 AM	58	Gabapentin 2	Gabapentin-d10 IS	1233 345	1500 00	82 22	2 13	1 02	2 10	4 637e5	☑
2453	QCHI	Quality Control	12/23/2020 5 11 43 AM	59	Gabapentin 1	Gabapentin-d10 IS	5333 032	6000 00	88 88	2 13	1 02	2 10	3 491e5	☑
2454	QCHI	Quality Control	12/23/2020 5 11 43 AM	59	Gabapentin 2	Gabapentin-d10 IS	4714 791	6000 00	78 58	2 13	1 02	2 10	3 491e5	☑
2551	QCLO	Quality Control	12/23/2020 7 08 40 AM	70	Gabapentin 1	Gabapentin-d10 IS	148 061	150 00	98 71	2 13	1 01	2 10	5 112e5	☑
2552	QCLO	Quality Control	12/23/2020 7 08 40 AM	70	Gabapentin 2	Gabapentin-d10 IS	154 585	150 00	103 06	2 13	1 01	2 10	5 112e5	☑
2600	QCMID	Quality Control	12/23/2020 7 17 40 AM	71	Gabapentin 1	Gabapentin-d10 IS	1364 457	1500 00	90 96	2 13	1 02	2 10	4 298e5	☑
2601	QCMID	Quality Control	12/23/2020 7 17 40 AM	71	Gabapentin 2	Gabapentin-d10 IS	1411 150	1500 00	94 08	2 13	1 02	2 10	4 298e5	☑
2649	QCHI	Quality Control	12/23/2020 7 26 40 AM	72	Gabapentin 1	Gabapentin-d10 IS	5417 497	6000 00	90 29	2 12	1 02	2 09	3 400e5	☑
2650	QCHI	Quality Control	12/23/2020 7 26 40 AM	72	Gabapentin 2	Gabapentin-d10 IS	5187 122	6000 00	86 45	2 12	1 02	2 09	3 400e5	☑



Index	Sample Name	Sample Type	Acquisition Date & Time	Vial Number	Component Name	IS Name	Calculated Concentration	Actual Concentration	Accuracy	Retention Time	Relative RT	IS Retention Time	IS Area	Used
216	CAL 2	Standard	12/24/2020 11 08 51 PM	66	Pregabalin 2	Pregabalin-d5 IS	49 715	50 00	99 43	2 10	1 01	2 08	5 393e5	☑
264	CAL 3	Standard	12/24/2020 11 17 51 PM	67	Pregabalin 1	Pregabalin-d5 IS	242 996	250 00	97 20	2 14	1 01	2 12	4 076e5	☑
265	CAL 3	Standard	12/24/2020 11 17 51 PM	67	Pregabalin 2	Pregabalin-d5 IS	271 367	250 00	108 55	2 14	1 01	2 12	4 076e5	☑
313	CAL 4	Standard	12/24/2020 11 26 50 PM	68	Pregabalin 1	Pregabalin-d5 IS	1009 025	1000 00	100 90	2 09	1 01	2 07	3 819e5	☑
314	CAL 4	Standard	12/24/2020 11 26 50 PM	68	Pregabalin 2	Pregabalin-d5 IS	970 951	1000 00	97 09	2 09	1 01	2 07	3 819e5	☑
362	CAL 5	Standard	12/24/2020 11 35 50 PM	69	Pregabalin 1	Pregabalin-d5 IS	2996 739	3000 00	99 89	2 09	1 01	2 06	3 169e5	☑
363	CAL 5	Standard	12/24/2020 11 35 50 PM	69	Pregabalin 2	Pregabalin-d5 IS	3010 178	3000 00	100 34	2 08	1 01	2 06	3 169e5	☑
2371	QCLO	Quality Control	12/23/2020 4 53 43 AM	57	Pregabalin 1	Pregabalin-d5 IS	42 141	37 50	112 38	2 10	1 01	2 07	4 708e5	☑
2372	QCLO	Quality Control	12/23/2020 4 53 43 AM	57	Pregabalin 2	Pregabalin-d5 IS	42 174	37 50	112 46	2 10	1 01	2 07	4 708e5	☑
2420	QCMID	Quality Control	12/23/2020 5 02 43 AM	58	Pregabalin 1	Pregabalin-d5 IS	355 952	375 00	94 89	2 09	1 01	2 08	4 507e5	☑
2421	QCMID	Quality Control	12/23/2020 5 02 43 AM	58	Pregabalin 2	Pregabalin-d5 IS	377 157	375 00	100 58	2 09	1 01	2 08	4 507e5	☑
2469	QCHI	Quality Control	12/23/2020 5 11 43 AM	59	Pregabalin 1	Pregabalin-d5 IS	1459 140	1500 00	97 28	2 09	1 01	2 08	3 825e5	☑
2470	QCHI	Quality Control	12/23/2020 5 11 43 AM	59	Pregabalin 2	Pregabalin-d5 IS	1456 426	1500 00	97 10	2 09	1 01	2 08	3 825e5	☑
2567	QCLO	Quality Control	12/23/2020 7 08 40 AM	70	Pregabalin 1	Pregabalin-d5 IS	41 324	37 50	110 20	2 09	1 01	2 07	4 627e5	☑
2568	QCLO	Quality Control	12/23/2020 7 08 40 AM	70	Pregabalin 2	Pregabalin-d5 IS	41 051	37 50	109 47	2 09	1 01	2 07	4 627e5	☑
2616	QCMID	Quality Control	12/23/2020 7 17 40 AM	71	Pregabalin 1	Pregabalin-d5 IS	386 736	375 00	103 13	2 09	1 01	2 07	4 106e5	☑
2617	QCMID	Quality Control	12/23/2020 7 17 40 AM	71	Pregabalin 2	Pregabalin-d5 IS	403 678	375 00	107 65	2 09	1 01	2 07	4 106e5	☑
2665	QCHI	Quality Control	12/23/2020 7 26 40 AM	72	Pregabalin 1	Pregabalin-d5 IS	1330 344	1500 00	92 02	2 08	1 01	2 06	3 692e5	☑
2666	QCHI	Quality Control	12/23/2020 7 26 40 AM	72	Pregabalin 2	Pregabalin-d5 IS	1455 696	1500 00	97 05	2 09	1 01	2 06	3 692e5	☑

Lena Portillo (s)

From: Joan Kosiek (s)
Sent: Tuesday, January 5, 2021 12 22 PM
To: Lena Portillo (s), Arthur M Zebelman PhD
Cc: Kelly Hock (s)
Subject: RE CAP Additional Documentation Request, Ref 10219

Lena, Dr. Zebelman and Kelly –
I have some comments to offer regarding the responses submitted by Averhealth Laboratories Cap # 8729023 and Complaint #10219.

- The director is very forward in her reactions to this complaint submitted by a previous employee – seen as financial gain by the complainant
- There are numerous PT issues in this laboratory – both qualitative and quantitative involving three different sample matrices (urine, oral fluid and hair). The data is from 2019 and 2020.

2019 – the investigation reports are not adequate to see repeat samples with results. The resolution for some errors was to repeat the sample and if the result fell within acceptable limits – the problem was resolved. The laboratory did not investigate the root cause of the original problem. The laboratory uses the CAP PT Exception report form to show documentation. One of the questions asks – Does review of past PT results indicate evenly distributed date without bias? The laboratory responded "Yes" A review of the bar graphs from the past three cycles of survey challenges clearly shows bias in one direction for numerous analytes.
UDC-A 2019 –Sample 08 MDA reported as 960; expected value – 648, repeat same value 960 – the laboratory changed the internal standard at this time. Errors also with hydrocodone and 6MAM. This analysis was completed and signed off by M Glinn on 2/15/19 however, the report states "staff training was completed on 3/6/19". This was documented as being done three weeks AFTER her original signoff of the investigation.
UDC-B 2019 – Samples 11-20 Creatinine ALL samples unacceptable – laboratory responded "unclear why they are low". Repeat was acceptable.
UDC-C 2019 – Samples 24-PCP, 25-EDDP, 28-6MAM, 29-THCCOOH – response – "all acceptable upon repeat" again no further investigation
UDC-D 2019 -Creatinine Again – repeat acceptable - note UDC B and UDC D same issue with creatinine

2020 –
UDC-A 2020 –Samples 01-MDMA, 06-oxycondone, 10- Benzoylecgonine – values submitted were at least half of the expected response – recalibrated and repeated – all accepted; urine pH 02, 06 and specific gravity UDC 1,5,6,9 all very low- laboratory went from manual reading to an instrument, technical errors!
UDC-B-2020 – Samples 11 hydromorphone, 12- PCP, 15- temazepam, 17-pH; Temazepam- the laboratory ordered a new standard – no results on report- also noted problems with the oral fluid temazepam

OFD-C 2019 – Amp group reported as neg, expected pos – repeat the same – no further explanation
OFD-D 2019- Benzoylecgonine – recal
OFD-A-20202 Nordiazepam – changed the internal standard; methadone – reported as neg – expected pos – laboratory stated 'Just below cutoff" The FDT survey has cutoffs that the laboratory Must attain.
OFD-B-2020 Samples 6 hydromorphone, 08 PCP, 09 Temazepam – laboratory stated "temazepam is extremely variable, compound is not stable" – question if they should be reporting this analyte?
OFD-C-2020 Samples 12- PCP (listed as a "sample issue");13 -methadone,14 methamphetamine-

Linearity set for Creatinine was run three different days – did not follow kit instructions for use within 1 hour of coming to room temperature
The reason I mention the specific analytes is that you can see REPEAT issues with the same analytes – not good follow-up with errors.

In regards to the request for investigation of bias – the laboratory does not understand Bias – they submitted instrument comparisons however we are asking them to look at the PT bar graphs and resolve a very obvious problem with being on the same side the mean every survey set. They also need to add this to their QM policy.

Hair Samples PT – the laboratory DID NOT provide or perform and evaluation of any of the challenges – some results were outside limits

Chart E1-11 – I leave that one for Dr. Zebelman to review as I am not experienced in this area.
Chart E 12-14 – noted that calibrators on the high end are excluded from the curves – question the reportable limit of those drugs – do they go beyond the recovered values (AMR) for Benzoylecgonine and oxymorphone?

OK, that is my analysis!!!
Joan

From: Lena Portillo (s) <LPORTIL@CAP.ORG>
Sent: Tuesday, January 5, 2021 9:04 AM
To: Arthur M Zebelman PhD <azebelman@gmail.com>
Cc: Joan Kosiek (s) <jkosiek@cap.org>; Kelly Hock (s) <khock@cap.org>
Subject: FW: CAP Additional Documentation Request, Ref 10219

Hello Dr. Zebelman,

Please find attached the laboratory response to the additional documentation request that was sent (also attached). Can you kindly review and provide your thoughts/comments? Joan K. will also be looking through the documentation. My initial thought is that the director has not really addressed anything nor does she see a problem.

Thank you for all your help, it is much appreciated!

Best,

Lena Portillo, MT(ASCP)
Investigations Analyst, CAP Accreditation Programs
College of American Pathologists
325 Waukegan Road, Northfield, IL 60093
lportil@cap.org
Tel: 800-323-4040 ext 7349 **Dir:** 847-832-7349 **Fax:** 847-832-8349
cap org | @pathologists | CAPconnect
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Lena Portillo (s)

From: Michael Peat <michael peat@att net>
Sent: Monday, January 11, 2021 3:42 PM
To: Joan Kosiek (s); Arthur M Zebelman PhD, Lena Portillo (s); Kelly Hock (s); R H Barry Sample PhD
Subject: Re: CAP Additional Documentation Request, Ref 10219

So, in all likelihood some of these PT failures etc. occurred before the 2.6.20 inspection? And the inspectors reviewed the responses to them on-site and did not comment?

I am leaning towards Art's suggestion as I know Michelle and trust her - hope she does not transition until she has picked the right person.

Mike

From: "Joan Kosiek (s)" <jkosiek@cap.org>
Date: Monday, January 11, 2021 at 3:38 PM
To: Michael Peat PhD <michael peat@att net>, Arthur M Zebelman PhD <azebelman@gmail com>, "Lena Portillo (s)" <LPORTIL@CAP.ORG>, "Kelly Hock (s)" <khock@cap.org>, "R H. Barry Sample PhD" <barry.x.sample@questdiagnostics.com>
Subject: RE: CAP Additional Documentation Request, Ref 10219

Hi, Dr. Peat!
The complaint was initiated on 11/4/20. The lab was inspected on 2/6/20 – 1 deficiency.
Joan

From: Michael Peat <michael.peat@att.net>
Sent: Monday, January 11, 2021 3:34 PM
To: Arthur M Zebelman PhD <azebelman@gmail.com>; Lena Portillo (s) <LPORTIL@CAP.ORG>; Joan Kosiek (s) <jkosiek@cap.org>; Kelly Hock (s) <khock@cap.org>; R.H. Barry Sample PhD <barry x.sample@questdiagnostics.com>
Subject: Re: CAP Additional Documentation Request, Ref 10219

For my information – when was this lab last inspected and did that inspection overlap with any of the incidents included in the investigation?

From: <azebelman@gmail com>
Date: Sunday, January 10, 2021 at 10:42 PM
To: "'Lena Portillo (s)'" <LPORTIL@CAP.ORG>, "'Joan Kosiek (s)'" <jkosiek@cap.org>, "'Kelly Hock (s)'" <khock@cap.org>, 'Michael Peat PhD' <michael.peat@att.net>, "'R.H. Barry Sample PhD'" <barry.x.sample@questdiagnostics.com>
Cc: <azebelman@gmail.com>
Subject: FW. CAP Additional Documentation Request, Ref 10219

Please find attached my opinions (in red in the Word document) relative to the responses of Dr. Michele Glinn of Averhealth Laboratory to Complaint #10219. I want to thank Joan Kosiek for her painstaking review of Dr. Glinn's responses. This laboratory has many quality assurance issues in the areas of quality control and proficiency testing. I

Lena Portillo (s)

From: Sample, Barry X <Barry.X.Sample@questdiagnostics.com>
Sent: Monday, January 11, 2021 3.53 PM
To: Arthur M Zebelman PhD; Lena Portillo (s); Joan Kosiek (s); Kelly Hock (s); Michael Peat PhD
Subject: RE. CAP Additional Documentation Request, Ref 10219

I agree with Dr. Zebelman. My comments are as follows:

- While from a PT perspective, there do not appear to be qualitative (i.e., pos/neg) errors. The imprecision and lack of quantitative accuracy suggests that relative to a cutoff, that qualitative reporting errors could exist.
- I share the concerns regarding the chromatographic separation.
- I am also concerned that even though the lab utilizes matched deuterated internal standards that they are suggesting the use of an un-related deuterated ISTD to resolve their quantification issues. Such an approach is contrary to standard industry practice and may lead to increased matrix effect issues which would also need evaluation
- The submitted data indicates a higher than expected variability on both the immunoassay screening (AU5400) for certain analytes (e.g., THC) as well as the confirmatory (LC-MS/MS) assays.

Happy to discuss further if we need to jump on a call.

Barry

From: azebelman@gmail.com <azebelman@gmail.com>
Sent: Sunday, January 10, 2021 11:42 PM
To: 'Lena Portillo (s)' <LPORTIL@CAP.ORG>; 'Joan Kosiek (s)' <jkosiek@cap.org>; 'Kelly Hock (s)' <khock@cap.org>; 'Michael Peat PhD' <michael peat@att.net>, Sample, Barry X <Barry.X.Sample@questdiagnostics.com>
Cc: azebelman@gmail.com
Subject: FW: CAP Additional Documentation Request, Ref 10219

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Please find attached my opinions (in red in the Word document) relative to the responses of Dr. Michele Glinn of Averhealth Laboratory to Complaint #10219. I want to thank Joan Kosiek for her painstaking review of Dr. Glinn's responses. This laboratory has many quality assurance issues in the areas of quality control and proficiency testing. I believe they need to be put on probation and required to institute more thorough follow up and resolution of their QA issues.

I would greatly appreciate Drs. Peat and Sample taking a look at the attached material.

Arthur M. Zebelman, Ph.D.
FDT Commissioner

From: Lena Portillo (s) <LPORTIL@CAP.ORG>
Sent: Tuesday, January 5, 2021 7:04 AM
To: Arthur M Zebelman PhD <azebelman@gmail.com>
Cc: Joan Kosiek (s) <jkosiek@cap.org>; Kelly Hock (s) <khock@cap.org>
Subject: FW: CAP Additional Documentation Request, Ref 10219

From: Giblin Jr., Phelim J.
To: Doane, Amanda (DHHS)
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports
Date: Friday, March 25, 2022 1:29:17 PM
Attachments: image004.png

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Awesome! Enjoy the rest of your Friday.
Best,
PHELIM J. GIBLIN JR.
Project Assistant

SIDLEY AUSTIN LLP
+1 312 456 4069
pgiblin@sidley.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Friday, March 25, 2022 12:28 PM
To: Giblin Jr., Phelim J. <pgiblin@sidley.com>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports
Thank you!!! I am in.

From: Giblin Jr., Phelim J. <pgiblin@sidley.com>
Sent: Friday, March 25, 2022 1:21 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports

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I just sent you a new link from sharefile, I believe it should be working now if you follow the same process.
Best,
PHELIM J. GIBLIN JR.
Project Assistant

SIDLEY AUSTIN LLP
+1 312 456 4069
pgiblin@sidley.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Friday, March 25, 2022 12:19 PM
To: Giblin Jr., Phelim J. <pgiblin@sidley.com>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports
I tried that and it did not send me anything.

From: Giblin Jr., Phelim J. <pgiblin@sidley.com>
Sent: Friday, March 25, 2022 1:17 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Stein, Scott D. <sstein@sidley.com>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports

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Hi Amanda,
Since I created a new account for you, you'll have to create a new password by clicking the 'forgot password' button below. Please let me know if you are still have having issues or have any other technical questions on this. Otherwise, I hope you have a nice weekend!

PHELIM J. GIBLIN JR.
Project Assistant

SIDLEY AUSTIN LLP
+1 312 456 4069
pgiblin@sidley.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Friday, March 25, 2022 12:12 PM
To: Stein, Scott D. <sstein@sidley.com>
Cc: Giblin Jr., Phelim J. <pgiblin@sidley.com>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports
OK. Thank you and have a great weekend.
Amanda

From: Stein, Scott D. <sstein@sidley.com>
Sent: Friday, March 25, 2022 1:11 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Giblin Jr., Phelim J. <pgiblin@sidley.com>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports

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I'm copying our legal assistant, who can help you with logistics. However, he's out today so it may not be until Monday.
SCOTT D. STEIN

SIDLEY AUSTIN LLP
+1 312 853 7520
sstein@sidley.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Friday, March 25, 2022 12:01 PM
To: Stein, Scott D. <sstein@sidley.com>
Cc: Amy Daniels (s) <adaniel@cap.org>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports
Scott,
It wants a password for me to retrieve the files.
Amanda

From: Stein, Scott D. <sstein@sidley.com>
Sent: Friday, March 25, 2022 12:46 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Amy Daniels (s) <adaniel@cap.org>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports

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Amanda, you (and Jennifer, Shayne, and Sara) should be able to access the documents here:
https://sidley.sharefile.com/home/myfiles/fo205940-a148-4931-96e1-f1a180cdaf9c
SCOTT D. STEIN

SIDLEY AUSTIN LLP
+1 312 853 7520
sstein@sidley.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Friday, March 25, 2022 8:06 AM
To: Stein, Scott D. <sstein@sidley.com>
Cc: Amy Daniels (s) <adaniel@cap.org>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports
Thank you very much. We look forward to receiving them.
Amanda

From: Stein, Scott D. <sstein@sidley.com>
Sent: Friday, March 25, 2022 8:42 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Amy Daniels (s) <adaniel@cap.org>
Subject: RE: Request for Averhealth/AverTest CAP-FDT Reports

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Good morning Amanda. We will provide a copy of the materials that we previously produced to DOJ. If there is something else specific you are seeking that is not in these materials, please let us know.
SCOTT D. STEIN

SIDLEY AUSTIN LLP
+1 312 853 7520
sstein@sidley.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Tuesday, March 22, 2022 8:27 AM
To: Amy Daniels (s) <adaniel@cap.org>
Cc: Warner, Jennifer (DHHS) <WarnerJ19@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>; Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: Request for Averhealth/AverTest CAP-FDT Reports
Importance: High
Good morning Amy,
I hope you are doing well this morning. I wanted to follow-up on our request for any information CAP has regarding Averhealth's accreditation, investigations, probationary status, and compliance with standards. I understand you indicated on a call last week that CAP would provide the information if requested in writing from a government agency. This is a follow-up request for that information.
Please let me know if you need anything else to fulfill this request.
Amanda Doane
Department Analyst
Bureau of Out-of-Home Services
Children's Services Agency
235 S. Grand Ave., Suite 510

Lansing, MI 48933
517-282-5273 work
DoaneA@michigan.gov

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From: Doane, Amanda (DHHS)
Sent: Friday, March 4, 2022 9:21 AM
To: Amy Daniels (s) <adaniel@cap.org>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: Request for Averhealth/AverTest CAP-FDT Reports

Amy,

Thank you for taking time on Wednesday to meet with us and discuss CAP-FDT and what information you could give us regarding accreditation of Averhealth/AverTest. The State of Michigan Children's Services Agency currently has a contract with Averhealth to provide forensic drug screening/testing for child welfare cases; specifically administered with parents involved with the Child Protective Services and foster care case management in the State of Michigan. We would like to request all inspection reports (including interim inspections) completed at the Averhealth/AverTest laboratory in St, Louis Missouri from June 2019, when we began contracting, to present. Our contract requires Averhealth's accreditation be in good standing so we would like to review these reports and any findings along with their response (if any).

Please let us know if you have any questions or need anything else from us.

Amanda Doane
Department Analyst
Bureau of Out-of-Home Services
Children's Services Agency
235 S. Grand Ave., Suite 510
Lansing, MI 48933
517-282-5273 work
DoaneA@michigan.gov

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Ex. 112

COLLEGE of AMERICAN PATHOLOGISTS

EXPRESS DELIVERY

CAP #: 8729023
AU ID: 1690070

January 29, 2021

Michele Glinn, PhD
Avertest LLC d/b/a Averhealth Laboratory
Suite 100
4709 Laguardia Dr
Saint Louis, Missouri 63134-3142

Dear Dr. Glinn:

This letter serves as notice that on January 27, 2021 the Accreditation Committee of the College of American Pathologists placed the accreditation of Avertest LLC d/b/a Averhealth Laboratory on **probation**. Pertinent regulatory agencies involved with this laboratory will be notified of this determination. This decision is based on the laboratory's lack of continuous compliance with Standard III – Quality Management, as documented during the review of documentation submitted in response to a complaint investigation.

The Accreditation Committee (AC) is especially concerned about the implementation of policies and procedures to correct the following substantiated allegations:

- Concern regarding unacceptable quality assurance of mass spectrometry confirmatory testing.
  - Related Checklist items: COM.01700 PT Evaluation; GEN.13806 QM Program
- Failure to follow procedures as written.
  - Related Checklist item: COM.10300 Knowledge of Policies and Procedures
- Concern regarding the manipulation of instrument calibrations.
  - Related Checklist items: FDT.02002 QC Confirmation of Acceptability; FDT.02030 QC Acceptance Criteria; FDT.02715 QC Corrective Action
- Concern regarding the review of quality control results.
  - Related Checklist items: FDT.02002 QC Confirmation of Acceptability; FDT.02030 QC Acceptance Criteria; FDT.02715 QC Corrective Action

The committee is particularly concerned about the evaluation of bias and root cause analysis in regard to proficiency testing results, as well as the use of historical QC and QC acceptance practices.

As a condition of continued accreditation and in order to allow the Committee to assess compliance with Standard III, the laboratory must:

Submit the following documentation by February 26, 2021:

- Provide a detailed explanation of when and how historical calibration curves and/or historical quality control are used.
  - If the laboratory ceases the use of historical calibration curves and/or historical quality control, submit a revised Quality Control Plan.
  - If the laboratory intends to continue the use of historical calibration curves and/or historical quality control, submit a comprehensive QC plan for this practice.

- Submit a procedure that defines a method of quantifying chromatographic peak tailing and institute defensible limits on what constitutes acceptable chromatography. The calculation of a tailing factor or an asymmetry factor with set limits is one approach that can be used.
    - Submit the signed Validation Summary for this method.
- Submit a re-evaluation of quantitative bias as shown in the bar graphs on all CAP UDC and OF Proficiency Testing surveys for 2019 and 2020, to include a corrective action plan for the bias.
- Submit a revised QC policy that requires that no results, positive or negative, are released if QC is not acceptable. This must also detail a corrective action plan for when there are QC failures.

Upon receipt of proficiency testing results for 2021, provide the following within 14 days for each proficiency testing event:

- Evaluation and corrective actions for all external proficiency testing for urine, oral fluid and hair testing.
    - The evaluations must include corrective actions for all qualitative and quantitative results that are less than the highest rating, outside of a standard deviation index of plus or minus 2.0, or any hair test result rated as “questionable” or “unsatisfactory.”

- **Undergo a successful unannounced non-routine inspection to be completed by May 27, 2021.** The non-routine inspection will be conducted using the 2020 checklist edition. This inspection will occur at the laboratory’s expense.

Submit the requested documentation by the dates specified above to Lena Portillo at CAP headquarters via mail, email (lportil@cap.org) or fax to 847-832-8349.

Failure to comply with these conditions of probation will result in review by the Accreditation Committee and possible additional sanctions up to and including revocation of accreditation.

The Laboratory will remain on probation until the Accreditation Committee determines that the conditions of probation have been successfully rectified. If you have any questions regarding the College’s decision, please contact Denise Driscoll, Sr. Director Accreditation and Regulatory Affairs, at 800-323-4040, ext. 7243.

Sincerely,

Michael B. Datto, MD, PhD, Accreditation Committee Chair

cc: Walter H. Henricks, MD, Chair, Commission on Laboratory Accreditation
Arthur M. Zebelman, PhD, Toxicology Commissioner
Michael Peat, PhD, Toxicology Central Region Commissioner
Denise Driscoll, Sr. Director, Accreditation and Regulatory Affairs
Jason Herzog, CEO, Avertest LLC d/b/a averhealth

Ex. 115

COLLEGE of AMERICAN PATHOLOGISTS

May 25, 2021

Reference Number: 10459
CAP Number: 8729023
AU ID: 1690070

Michele Glinn, PhD
Avertest LLC d/b/a averhealth
Averhealth Laboratory
Suite A
2916 W. Marshall St
Richmond, VA 23230

Dear Dr. Glinn:

The College of American Pathologists' (CAP) Accreditation Programs has reviewed the inspector findings concerning the complaint that we received. The allegations were reviewed and determined to be not applicable to the testing performed under the CAP FDT program.

Please remember that CAP accreditation is not a substitute for the Laboratory's and its personnel's continuous in-depth monitoring which is essential to a safe and properly functioning laboratory. If you have any questions, please contact Amy Daniels, Technical Director, Accreditation Services at 800/323-4040, extension 7471.

Sincerely,

Earle S. Collum, MD, Complaints and Investigations Committee Chair
CAP Accreditation Programs

ESC/ajd

cc: Walter H. Henricks, MD, Chair, Commission on Laboratory Accreditation
Arthur M. Zebelman, PhD, Regional Commissioner
Amy Daniels, Technical Director, Accreditation Services

325 Waukegan Rd.
Northfield, IL 60093
800-323-4040 | cap.org

Ex. 116

COLLEGE of AMERICAN PATHOLOGISTS

CAP #: 8729023
AU ID: 1690070
Reference # 10219
July 29, 2021

Michele Glinn, PhD
Avertest LLC d/b/a Averhealth Laboratory
Suite 100
4709 Laguardia Dr
Saint Louis, Missouri 63134-3142

Dear Dr. Glinn:

This letter serves as notice that on July 28, 2021, the Accreditation Committee of the College of American Pathologists removed probation from the accreditation of Avertest LLC d/b/a Averhealth Laboratory. Pertinent regulatory agencies involved with this laboratory will be notified of this determination. This decision is based on review of the report of the non-routine inspection conducted on May 13, 2021. In order to ensure ongoing compliance, your laboratory is accredited with the following requirements:

- **Submit evaluations and corrective actions for all external proficiency testing for urine, oral fluid, and hair testing to include investigation of bias.**
  - **Submission expected within 14 days of receipt of PT results, to continue until the laboratory's next routine inspection in 2022.**
- **Submit 2 quarters of evidence of QC review with documentation of follow-up for any QC issues.**
  - **First submission expected by October 12, 2021.**
  - **Second submission expected by January 11, 2022.**

Submit the requested documentation by the dates specified above to Lena Portillo at CAP headquarters via mail, email (lportil@cap.org), or fax to 847-832-8349.

The College of American Pathologists' (CAP) Accreditation Program has also completed its review of complaint reference number 10219. This letter verifies that the allegations are being appropriately addressed and laboratory compliance will be monitored with the requirements as stated above. This complaint has been closed.

Our investigation determined that the laboratory was out of compliance with the CAP Standards for Laboratory Accreditation with respect to the following allegations:

- Concern regarding unacceptable quality assurance of mass spectrometry confirmatory testing.
- Failure to follow procedures as written.
- Concerns regarding the manipulation of instrument calibrations.
- Concerns regarding the review of quality control results.

The most recent inspector confirmed significant progress in correcting deficiencies identified during investigation of complaint #10219, and we appreciate the efforts made to demonstrate improvements. Please note, however, that accreditation is a continuous process. The laboratory director must assure compliance with all accreditation requirements. At the laboratory's next routine inspection, the inspector will be looking for continuous compliance with all accreditation requirements, including those that have been cited as deficient in recent inspections. Please remember that CAP accreditation is not a substitute for the laboratory's and its personnel's continuous in-depth monitoring which is essential to a safe and properly functioning laboratory.

The CAP is required to report substantiated complaints to oversight agencies. Such agencies may contact the CEO or other administrative officers of your organization regarding this matter. If you have any questions regarding the complaint process, please contact Amy Daniels, Technical Director, Accreditation Services at 800/323-4040, extension 7471.

If you have any questions regarding the College's decision, please contact Denise Driscoll, Sr. Director Accreditation and Regulatory Affairs, at 800-323-4040, ext. 7243.

Sincerely,

Michael B. Datto, MD, PhD, Accreditation Committee Chair

MBD/ESC/lmp/MAW

cc: Walter H. Henricks, MD, Chair, Commission on Laboratory Accreditation
Arthur M. Zebelman, PhD, Toxicology Commissioner
Earle S. Collum, MD, Complaints and Investigations Committee Chair
Michael Peat, PhD, Toxicology Central Region Commissioner
Jason Herzog, CEO, Avertest LLC d/b/a Averhealth
Denise Driscoll, Sr. Director, Accreditation and Regulatory Affairs
Amy Daniels, Technical Director, Accreditation Services

From: Campau, Wendy (DHHS)
To: Starling, Demetrius (DHHS); Machen, Shayne (DHHS)
Subject: FW: Averhealth contract Attorney Client Privilege
Date: Monday, March 7, 2022 5:25:56 PM
Attachments: image001.gif
image002.jpg
image003.png

Well that escalated quickly Shayne, do you want me to set up or will you take it from here?

Wendy Campau
(COM-POH) Pronouns: she/her PRONOUNS MATTER
517-230-3765
Chat with me on Teams

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From: Sanches, Christine (DHHS) <SanchesC@michigan.gov>
Sent: Monday, March 7, 2022 5:03 PM
To: Campau, Wendy (DHHS) <CampauW@michigan.gov>
Cc: Smith, Terri (DHHS) <SmithT42@michigan.gov>; Knezek, David (DHHS) <KnezekD@michigan.gov>; Hanley, Farah (DHHS) <hanleyf@michigan.gov>; Weber, Andrea (DHHS) <WeberA9@michigan.gov>; Smith, Erin (DHHS) <SmithE52@michigan.gov>
Subject: FW: Averhealth contract Attorney Client Privilege
Importance: High

Wendy,

I suggest MDHHS Legal Affairs be involved in the conversation as well as DTMB Central Procurement Services since this is a DTMB administered contract. DTMB may also want their legal counsel at the meeting.

Andrea Weber is the BGP Senior Executive Management Assistant and can assist with scheduling on behalf of Terri and I.

As Terri stated previously, DTMB administers MA 19*0690 on our behalf with Avertest, LLC dba Averhealth – see contract link below. The vendor provides drug screening and confirmation testing (oral and urine) and/or alcohol testing for MDHHS clients. MDHHS CPS workers/foster care workers,

private agency child welfare partners, and third-party administrators collect samples from clients on a randomized testing schedule. The current contract value is $27,318,750.00.

Contract Link

Chris

Christine H. Sanches
Michigan Department of Health & Human Services
Financial Operations Administration
Director, Bureau of Grants & Purchasing
235 S. Grand Ave., Suite 1201
Lansing, MI 48933
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From: Campau, Wendy (DHHS) <CampauW@michigan.gov>
Sent: Monday, March 7, 2022 4:57 PM
To: Sanches, Christine (DHHS) <SanchesC@michigan.gov>; Smith, Terri (DHHS) <SmithT42@michigan.gov>
Cc: Warner, Jennifer (DHHS) <WarnerJ19@michigan.gov>; Pitchford, Ann (DHHS) <PitchfordA@michigan.gov>
Subject: Averhealth contract Attorney Client Privilege
Importance: High

Hello:
We have been contacted by the US Attorney General regarding allegations against Averhealth. We believe we need to discuss the circumstances and movement to terminate the contract. Can Andrea assist finding time for us and who should be included on your end?

Thanks.

Wendy Campau, MSW
(COM-POH) Pronouns: she/her PRONOUNS MATTER
Bureau of CSA Administration Director
MDHHS Children's Services Agency
517-230-3765

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From:	Machen, Shayne (DHHS)
To:	Sesti, Kelly (DHHS); Doane, Amanda (DHHS); Willis, Rachel (DHHS); Click, Tim (DHHS); Warner, Jennifer (DHHS)
Cc:	Goad, Sarah (DHHS); Rosenberg, Michael (DHHS)
Subject:	RE: Averhealth Billing Numbers
Date:	Wednesday, March 9, 2022 11:05:00 AM
Attachments:	image001.png

+Jen Warner

From: Sesti, Kelly (DHHS) <SestiK@michigan.gov>
Sent: Wednesday, March 9, 2022 11:02 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>; Rosenberg, Michael (DHHS) <RosenbergM2@michigan.gov>
Subject: RE: Averhealth Billing Numbers

Amanda,
Could you contact Averhealth and ask for a master list (not separated by tab) including the county and district? Basically the same list they provided yesterday not separated. We will also need them to add all test results and dates.

To obtain the number of impacted cases, we can't total each tab because that will only give us the number of people tested not the number of cases because multiple people on one cases could have been tested- make sense? We will use the master list to identify the cases in the data warehouse.

Thanks,
Kelly

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Wednesday, March 9, 2022 10:47 AM
To: Machen, Shayne (DHHS) <MachenS@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

Oops – I forgot about FY22 number to date. I have added them in below.

From: Doane, Amanda (DHHS)

Sent: Wednesday, March 9, 2022 10:43 AM
To: Machen, Shayne (DHHS) <MachenS@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

The following are the number of tests by fiscal year.

Fiscal Year	Tests by DHHS	Test by Private Partners	Tests by TPAs	Tests by Mobile collectors
2019	7639	540	12076	1487
2020	27010	3683	39360	7863
2021	20542	11869	49832	10444
2022 (to date)	8028	2995	16633	3581

- Tests by DHHS are samples collected by MDHHS staff only – we pay $28.00 per test
- Tests by Private Partners are collected by private agency foster care staff only – we pay $28.00 per test
- Tests by TPAs are collected by a third party "brick and mortar" location used for randomization – we pay an additional $29.50 for each of these in addition to the $28.00 lab fee.
- Tests by Mobile Collectors are by a third party and the collector goes to the client when the client does not have access to a brick and mortar location. We pay an additional $29.50 for this plus the $28.00 lab fee PLUS standard mileage rates (paid per mile).
- Please note the 2022 numbers are through 2/28/22

Please let me know if you need additional information.

Amanda

From: Machen, Shayne (DHHS) <MachenS@michigan.gov>
Sent: Wednesday, March 9, 2022 10:10 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

Hi Amanda,

Can you please tell us what the total for this data is? How many cases total do we have? This looks like it only tells us the number of cases and not the number of tests. Is there a way to get the total number of tests done since then?

Sha

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Tuesday, March 8, 2022 7:13 AM
To: Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers
Importance: High

Attached is the list from Averhealth of all clients who have been tested since the beginning of the contract. Each County has its own tab.

The workbook contains the following information:

- Client name
- Birthdate
- Gender
- Race
- Averhealth ID#
- If they test on a random basis (how many times per week/month) or if they test manually with their caseworker
- Date they were entered into Aversys
- Date their profile was last updated
- What kind of panel they test for
    - MDHHS/PPA Oral = caseworker collects sample
    - TPA Oral = client goes to TPA for collection or has mobile collection
- Date of last test
- Date of last positive test
- Location of collection
    - Either a county worker or TPA location

The rest of the columns are not always completed as this was a pre-canned report so we would not have to wait for Averhealth to build another report specifically for my request. If you want other information please let me know and I will ask for a different report to be built.

Amanda

From: Willis, Rachel (DHHS) <WillisR4@michigan.gov>
Sent: Monday, March 7, 2022 10:48 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

If they could pull them all, that would be ideal.

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Monday, March 7, 2022 10:11 AM
To: Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

The portal is where workers go to enter clients, assign random testing, retrieve results, etc. I can have Averhealth run me a report that lists all clients (maybe by county) who have tested. I would need a time period to ask for or just pull them all?

Amanda

From: Sesti, Kelly (DHHS) <SestiK@michigan.gov>
Sent: Monday, March 7, 2022 9:56 AM
To: Click, Tim (DHHS) <ClickT@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

After speaking with the field and Rachel Friday, I believe she is finding out what data is in the portal or Amanda, maybe you can let the group know?

At this point, I don't believe there is not a space in MiSACWIS that we could accurately pull data from but plan to meet with DMU about this in a few minutes.

From: Click, Tim (DHHS) <ClickT@michigan.gov>
Sent: Monday, March 7, 2022 9:53 AM
To: Machen, Shayne (DHHS) <MachenS@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>
Subject: RE: Averhealth Billing Numbers

I wonder if there is a way to get this information from the "results" portal that workers use to get results after a test has been sent in?

Tim

From: Machen, Shayne (DHHS) <MachenS@michigan.gov>
Sent: Friday, March 4, 2022 2:22 PM
To: Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>; Sesti,

Kelly (DHHS) <SestiK@michigan.gov>
Subject: RE: Averhealth Billing Numbers

I've asked Kelly Sesti to see if there is a way to collect this information within our current IT systems. She's considering what options we have.

Shayne

From: Willis, Rachel (DHHS) <WillisR4@michigan.gov>
Sent: Friday, March 4, 2022 1:57 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>
Subject: RE: Averhealth Billing Numbers

Hi Amanda,

This makes sense. I didn't realize that from the billing purposes you handle a twice monthly role up payment. This means that we need to get a list of payment authorizations from the county level. We are trying to determine how many cases have an aver health payment tied to it. I m copying Tim Click on this e-mail as I will be working with him to figure out how to get our hands on this information.

Thanks!

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Thursday, March 3, 2022 11:19 AM
To: Willis, Rachel (DHHS) <WillisR4@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

Rachel,

I am a bit confused on what billings you are asking for. Averhealth is not paid via 93's as they submit billing to me twice per month and I process the payment for all the drug screens they did for us throughout the state.

Amanda

From: Willis, Rachel (DHHS) <WillisR4@michigan.gov>
Sent: Wednesday, March 2, 2022 2:14 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>

Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth Billing Numbers

Sarah-

Thanks for the update- If we can get the documents from the UAG, that would be great- is Carl out point of contact there?

Next steps related to the billings- Amanda, can you work with Teddy J. to get a list of all of the 93's/bills that were paid to averhealth since 2019? We would need the MiSACWIS case ID and county that paid on one long spreadsheet.

Thanks!

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Wednesday, March 2, 2022 8:19 AM
To: Machen, Shayne (DHHS) <MachenS@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Averhealth Billing Numbers
Importance: High

Rachel and Shayne,

Attached is a spreadsheet I put together this morning of all the billings from Averhealth since the beginning of the contract. The first invoice came in June 2019 so I included that month as well instead of only starting in July 2019.

Please note the following:

1. Averhealth used to bill three times per month. Billing was for testing done from the 1st through the 10th, 11th through the 20th, and 21st through the 31st. We set it up like that because I needed to be able to have the total invoice less than $250K as that was Steve's signature cap and I knew I had easy access to him on a consistent basis and would not need to go higher than him for signatures. After billing with Averhealth for a while we realized that we could go to twice per month billing and still keep the invoice below his signature threshold so now they bill for tests from the 1st through the 15th and the 16th through the 31st.
2. The amount paid column does not reflect the 1% discount we get if the invoice is paid within 10 business days. SIGMA does not show me that number…I only see the amount before the discount. We have only missed the discount window a few times (maybe six times). A couple of times it got lost in Accounting an was not processed in time and each end of fiscal year all payments are halted before the invoice can get paid.
3. The Mobile Tester Mileage Paid column does NOT receive the quick pay discount as this is the actual amount that Averhealth pays per mile to their mobile collectors. This acts as a pass-through so no discount is given. They now bill for this once monthly.

4. The COVID-19 pandemic shows itself in these numbers as well. From mid-March 2020 through mid-June 2020 the numbers are much lower as we had instructed staff to suspend most drug screens. I believe only CPS was doing screens at that time and no mobile testing was being completed.

Please let me know if you have any other questions.

Amanda Doane
Department Analyst
Bureau of Out-of-Home Services
Children's Services Agency
235 S. Grand Ave., Suite 510
Lansing, MI 48933
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DoaneA@michigan.gov

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From: Doane, Amanda (DHHS)
To: Goad, Sarah (DHHS); Parks, Colin (DHHS); Bladen, Stacie (DHS)
Subject: Figures for Monday meeting in Stacie"s Office
Date: Sunday, February 9, 2020 2:39:56 PM
Attachments: image001.png

I think we should anticipate some additional push-back from legislators and DHHS management on the contract we have with Averhealth. Some may question if the savings we are seeing is relevant and I wanted to give you actual numbers and money we have saved the state by utilizing Averhealth instead of the previous contractor. The following numbers are for FY2020 only as we fully transitioned to Averhealth on August 30th. These numbers are more accessible and have better meaning (I feel) from October 1st through January 30th. This constitutes 4 months or 1/3 of the fiscal year. The Averhealth numbers are actual numbers of what we have utilized and spent and the Forensic Fluid numbers are what we would have spent if we had gone with that company.

Collected By	Company	Price	Number of (oral fluid & urine)	Subtotal
MDHHS/Private Partners	Averhealth	$29.00ea	15,686	$454,894
TPA's	Averhealth	$57.50ea	19,892	$1,143,790
Mobile Mileage	Averhealth	$0.34/mile	78,076 miles	$26,545.84

$1,625,229.84 Total spent YTD FY2020

The following are costs if we had chosen FFL to be the contractor

Collected by	Company	Price	Number of	Subtotal
MDHHS/Private Partners	Forensic Fluids	$30.50ea	15,686	$478,423
TPAs (oral fluid)	Forensic Fluids	$65.50ea	19,376	$1,269,128
TPA (urine)	Forensic Fluids	$170.00ea	516	$87,720
Mobile Mileage	Forensic Fluids	$0.59/mile	78,076 miles	$46,064.84

$1,881,335.84 Total would have been spent YTD FY2020

YTD savings of $256,106 with a projected annual savings of $768,318

When we sent the service out to bid, we also anticipated approximately 150K test per year. This was based on prior years numbers of actual samples tested. This year we are on target to reduce that number and I anticipate we will come in somewhere around 110K (+/-) samples. Based on these

projections I anticipate to spend somewhere in the neighborhood of $4.5M of the $5.4 we have contracted to spend.

I cannot guarantee we will come in at these numbers but that is the spending trend we are on. I will be happy to discuss any or all of this in tomorrow's call.

Amanda Doane
Department Analyst
Office of Child Welfare Policy & Procedure
Children's Services Agency
235 S. Grand Ave., Suite 510
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Averhealth Caseworker Survey

This survey was developed by CPS Program Office to address concerns raised by front line staff (both public and private) and the courts regarding the Averhealth substance screen testing. This summary includes a summary of written concerns provided by our staff, a summary of concerns with our former substance use provider (Forensic Fluids) and recommendations for how to address these concerns moving forward.

Concerns:

- Averhealth website was identified as "not be user friendly", that it "crashes", and "needs filters".
    - Workers report they do not have a way to update referrals or client phone numbers once a referral was made.

  Suggested response: Some of this is a training issue. The Averhealth website can filter and address many of the concerns. Averhealth may have ideas on how to make the website less clunky.
- Chain of custody concerns
    - Many people indicated confusion on what was needed to be completed on the form.
    - Data entry into the system was identified as causing delay
    - Paper used to pre-print chain of custody information was reported to be problematic.

  Suggested response: This is seen primarily as a training/adoption issue. Various training approaches could resolve these concerns, including:
    - Redesign of the form.
    - Adopt mobile application (in process now with DTMB).
    - Training would assist workers being able to enter a client into the system.
- Additional and ongoing training is needed
    - New Averhealth system and a better understanding of the test submissions and understanding results are needed throughout the state.
    - Training is needed on a continual basis. Many training concerns revolved around new workers not being trained.

  Suggested response: Averhealth should survey staff on a continuous basis and train to any gaps identified in the surveys.
- Customer service concerns
    - Workers would like the ability to contact Averhealth directly by phone to discuss results.

  Suggested response: Averhealth needs to maintain an effective and responsive worker hotline, that workers may call at any time to receive necessary assistance.
- TPA concerns
    - Workers would like to have access to a mobile collector / TPA by phone to ask questions if needed / update information.
    - Concerns regarding TPAs indicating clients refused to screen when unable to be contacted were noted.
    - Hours of TPAs are not always helpful to clients who must work.

    - More TPAs and mobile TPAs were requested so counties can have multiple locations.
    - TPAs may benefit from additional training.

  Suggested response: Allow workers the ability to connect directly with TPA's as needed to address any concerns that may come up. Averhealth can use survey results to assess if these concerns are getting resolved.
- Report concerns
    - Reports are difficult to understand (including, but not limited to "no-show" reports).
    - Workers would like to discuss screen results with customer service to help interpret the results.

  Suggested response: Customer service hotline will allow for workers to discuss reports and receive guidance directly with Averhealth staff.
- Missing/misplaced screens
    - Averhealth was reported to have misplaced or lost screens. These issues have been discussed with Averhealth and any issues shared with CPS Program Office have been resolved through collaboration with Averhealth.
    - One county reported it had tracked their own screens, reporting that Averhealth had different information on shipping receipts then the local office did.

  Suggested response: All concerns regarding missing screens should be reported immediately to CPS Program Office. We will work with Averheatlh to address these concerns. In 20201, Averhealth will provide an online worker application to assist in tracking the submission of the screens to their completion.
- Timeframe/shipping concerns. Although survey responses identified that time frames have improved, other concerns remain
    - Three specific complaints were identified:
        - Delays in TPA's sending tests to Averhealth
        - Desire for other shipping options (based on local provider reliability in certain areas).
        - Delay's in local office shipping tests to Averhealth.
    - Perception of timeframes (workers misunderstood result timeframes began when the tests were shipped out, rather than when they are received by the lab).
    - Many comments indicated timeframes had improved since the beginning of the contract.
    - User error issues with chain of custody (time frames for registering a client still causes delay).

  Suggested response: Averhealth help line should also include a phone contact to help identify if a test has been received and timelines for results.
- Accuracy of test results and court concerns
    - These two complaints were often related.
        - Courts and attorneys have identified concerns regarding accuracy of the screening results.
        - Workers indicated they had clients admit to using and then receiving negative test results.
        - Oral screen test results completed by Averhealth and another tester have provided different results.

Suggested response: Variance between test results appear to be due from different testing levels of different testers and the very low testing levels established in the contract and tested for by Averhealth. It seems the most effective response would be to set oral test levels in accordance with an accredited body, specifically the CAP-FDT testing levels discussed with CSA.

Summary of Concerns with Previous Screening Tester, Forensic Fluids:

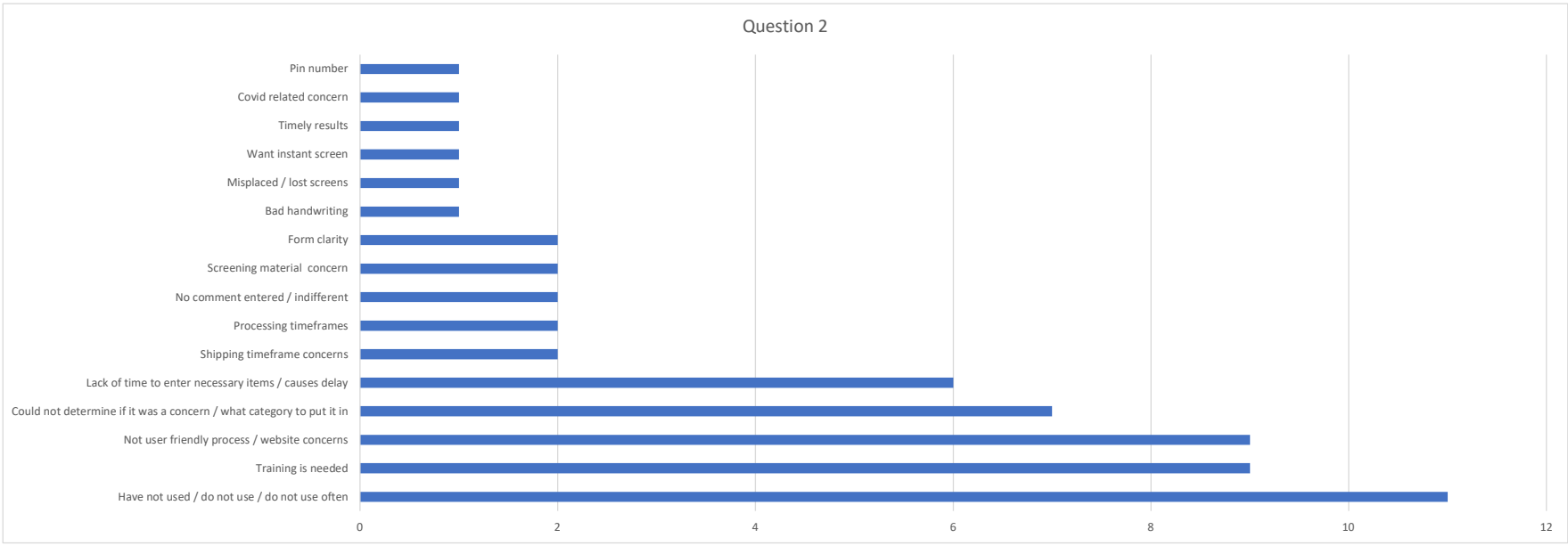
- Additional training
    - Training on the Forensic Fluids system system, collection process, and substance use information were regularly requested throughout the state.
    - Training was needed on a continual basis. Many training concerns revolved around new workers not being trained.
- Customer service concerns
    - Timeframes regarding responses and/or lack thereof were made.
- TPA concerns
    - Hours of TPAs are not always helpful to clients who must work.
    - More TPAs and mobile TPAs were requested so counties can have multiple locations.
    - TPAs may need additional training.
    - Concerns regarding quality of TPAs.
    - Concerns regarding TPAs following the correct process for obtaining screens.
    - Larger concerns were noted with TPAs under forensic fluids including tampering with tests, having sexual contact with clients, being unwilling to work with clients regarding screening times, and chain of custody concerns.
- Missing/misplaced screens
    - Forensic Fluids was reported to have misplaced or lost screens.
- Timeframe/shipping concerns
    - These two complaints often were related.
        - TPAs were reported to not ship samples to the lab quickly.
        - Several counties wanted different shipping options as current provider was not reported to be reliable in certain areas. This has been addressed.
        - Local offices do not always send samples in timely which can lead to delay.
- Accuracy of test/court concerns
    - These two complaints were often related.
        - Courts/attorneys were reported to have concerns regarding accuracy of the screening results.
        - Workers indicated they had clients admit to using and screen negative.
        - Results between Forensic Fluids oral swabs and screens completed by a different entity have been different.
- Supplies
    - Local offices often ran out of supplies to screen clients. Requests for more supplies were not always addressed timely.
- Testimony
    - Forensic Fluids did not testify when requested to do so on at least one occasion.

Next Steps:

1. Provide survey results with Averhealth for review and action.
2. Require Averhealth to conduct ongoing field survey work to assess how they are addressing the concerns of the field and the court.
3. Provide survey metrics to CSA and others as needed to identify these gaps are being addressed.
4. Request Averhealth report to staff and courts a variety of changes they will be making to better address these concerns, specifically to:
    a. Modify training to address current needs of field and court.
    b. Revise website for worker usability.
    c. Changes in chain of custody process in the interim as DTMB is working to approve Averhealth worker app.
    d. Changes to existing reports, including allowing for multiple reports, listing of high screening levels as well as other reports based on worker/court needs.
    e. Discuss current tracking of screens to determine if there are any gaps in tracking / process improvements needed.
    f. Address shipping concerns based on the survey comments.
    g. Determine how to meet timeframe compliance for those screens which are being uploaded after 24/48 hours.
    h. Discuss perception of inaccurate results and how to combat this.
5. Ensure TPAs have hours which allow those working to screen; Expand current brick and mortar TPA list. Mobile TPAs should still be used.
6. Require Averhealth create job aids if not created already. If they are created, ensure these are sent out to local POCs.
7. Work to change levels to CAP-FDT.

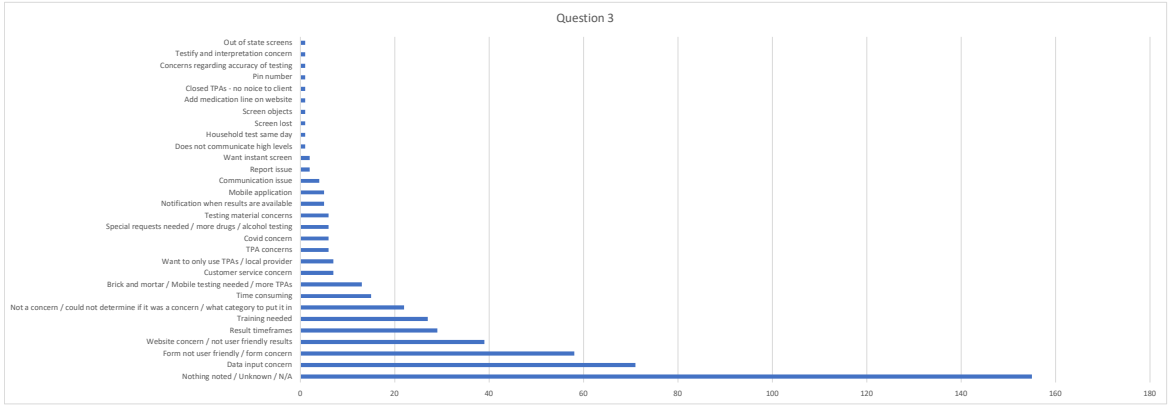
Do you find the process for collecting, porcessing and submitting screens (select all that apply): other

Have not used / do not use / do not use often	Training is needed	Not user friendly process / website concerns	Could not determine if it was a concern / what category to put it in	Lack of time to enter necessary items / causes delay	Shipping timeframe concerns	Processing timeframes	No comment entered / indifferent	Screening material concern	Form clarity	Bad handwriting	Misplaced / lost screens	Want instant screen	Timely results	Covid related concern	Pin number
11	9	9	7	6	2	2	2	2	2	1	1	1	1	1	1



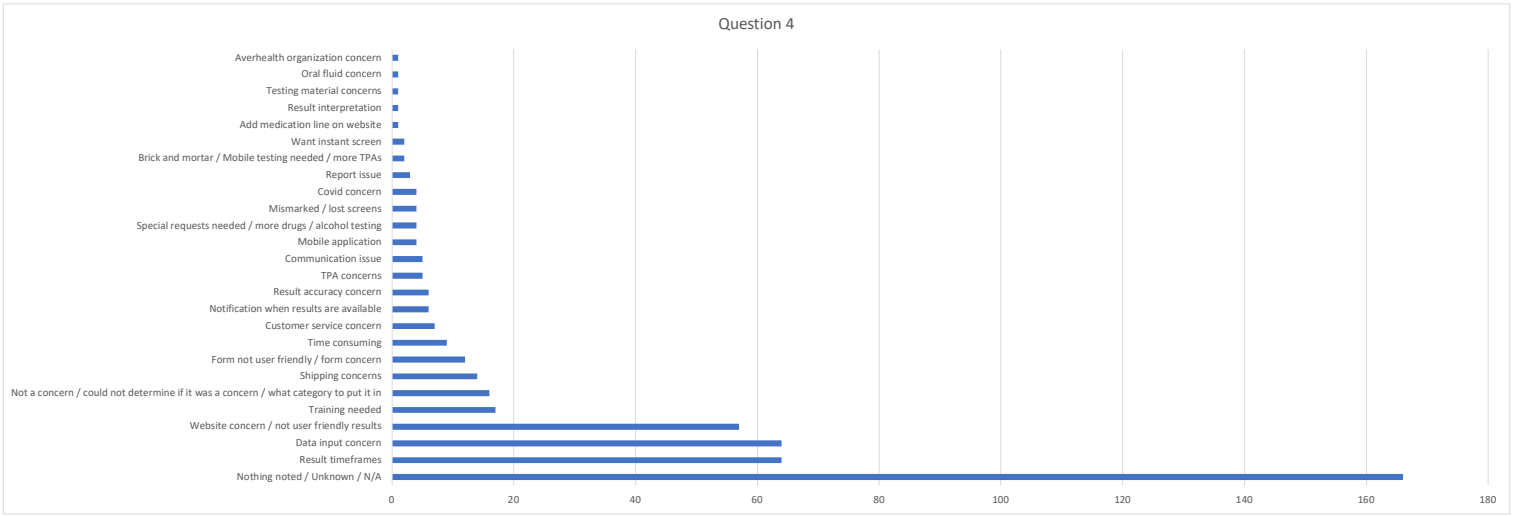
What changes would you suggest regarding the Averhealth screening collection process?

Nothing noted / Unknown / N/A	Data input concern	Form not user friendly / form concern	Website concern / not user friendly results	Result timeframes	Training needed	Not a concern / could not determine if it was a concern / what category to put it in	Time consuming	Brick and mortar / Mobile testing needed / more TPAs	Customer service concern	Want to only use TPAs / local provider	TPA concerns	Covid concern	Special requests needed / more drugs / alcohol testing	Testing material concerns	Notification when results are available	Mobile application	Communication issue	Report issue	Want instant screen	Does not communicate high levels	Household test same day	Screen lost	Screen objects	Add medication line on website	Closed TPAs - no noice to client	Pin number	Concerns regarding accuracy of testing	Testify and interpretation concern	Out of state screens	Shipping concerns
155	71	58	39	29	27	22	15	13	7	7	6	6	6	6	5	5	4	2	2	1	1	1	1	1	1	1	1	1	1	1



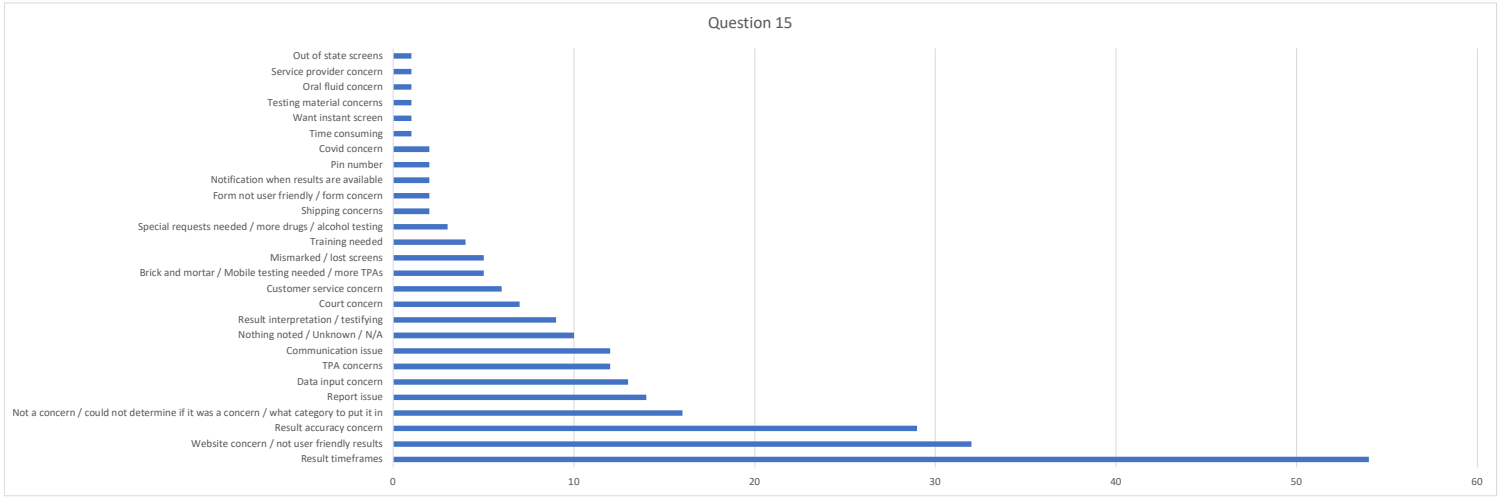
What changes would you suggest regarding the Averhealth screening sumission process?

Nothing noted / Unknown / N/A	Result timeframes	Data input concern	Website concern / not user friendly results	Training needed	Not a concern / could not determine if it was a concern / what category to put it in	Shipping concerns	Form not user friendly / form concern	Time consuming	Customer service concern	Notification when results are available	Result accuracy concern	TPA concerns	Communication issue	Mobile application	Special requests needed / more drugs / alcohol testing	Mismarked / lost screens	Covid concern	Report issue	Brick and mortar / Mobile testing needed / more TPAs	Want instant screen	Add medication line on website	Result interpretation	Testing material concerns	Oral fluid concern	Averhealth organization concern
166	64	64	57	17	16	14	12	9	7	6	6	5	5	4	4	4	4	3	2	2	1	1	1	1	1



Please indicate any specific concerns with Averhealth based on personal experience.

Result timeframes	Website concern / not user friendly results	Result accuracy concern	Not a concern / could not determine if it was a concern / what category to put it in	Report issue	Data input concern	TPA concerns	Communication issue	Nothing noted / Unknown / N/A	Result interpretation / testifying	Court concern	Customer service concern	Brick and mortar / Mobile testing needed / more TPAs	Mismarked / lost screens	Training needed	Special requests needed / more drugs / alcohol testing	Shipping concerns	Form not user friendly / form concern	Notification when results are available	Pin number	Covid concern	Time consuming	Want instant screen	Testing material concerns	Oral fluid concern	Service provider concern	Out of state screens
54	32	29	16	14	13	12	12	10	9	7	6	5	5	4	3	2	2	2	2	2	1	1	1	1	1	1



From: Parks, Colin (DHHS)
To: Lovell, Luther (DHHS)
Cc: Doane, Amanda (DHHS)
Subject: RE: Information regarding AVERSYS Laboratories
Date: Wednesday, October 14, 2020 2:54:31 PM

Not yet. We are working with SCAO/CSA leadership and Averhealth and hope to have updates in 2-3 weeks. If there are any concerns regarding Averhealth, please have counties connect with Amanda Doane and she can assist.

From: Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Sent: Wednesday, October 14, 2020 3:44 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: FW: Information regarding AVERSYS Laboratories

See below

From: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>
Sent: Wednesday, October 14, 2020 3:08 PM
To: Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Subject: RE: Information regarding AVERSYS Laboratories

Good afternoon,
Is there an update on how the meeting with the Judges and SCAO went on AVERSYS?

From: Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Sent: Friday, September 25, 2020 10:33 AM
To: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>
Subject: RE: Information regarding AVERSYS Laboratories

It's a conversation taking place at the CSA level. If you have examples please send them to me!

From: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>
Sent: Friday, September 25, 2020 10:15 AM
To: Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Subject: FW: Information regarding AVERSYS Laboratories

Have you heard more on this questioning from the Courts? I have asked our Foster Care staff to provide me case specifics on this with the Grand Traverse County Judge, as they have dismissed the positive drug tests.

From: Willson, Jeffrey (DHHS) <WillsonJ1@michigan.gov>
Sent: Friday, September 25, 2020 8:06 AM
To: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>
Cc: Lafontaine, Joncie (DHHS) <LafontaineJ@michigan.gov>; Hessem, Amanda (DHHS)

<HessemA@michigan.gov>
Subject: FW: Information regarding AVERSYS Laboratories

Hi Kris,

Regarding the email below, the Kalkaska court administrator is now inquiring about false positives from Averhealth testing, as our judge has heard other counties are having a problem. Specifically, she is questioning:

"Have you heard much about there be accuracy issues? Judge Buday is hearing from other Judges in other Court that they are finding the results unreliable?"

Considering the information below, I figured I better pass this on to you. Please let me know how you would like me to proceed with the court's question.

From: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>
Sent: Tuesday, September 22, 2020 10:34 AM
To: Culbertson, Sara (DHHS) <CulbertsonS@michigan.gov>; Garcia, Lisa (DHHS) <GarciaL2@michigan.gov>; Heethuis, Megan (DHHS) <HeethuisM@michigan.gov>; Lafontaine, Joncie (DHHS) <LafontaineJ@michigan.gov>; Menzel, Alexandra (DHHS) <MenzelA@michigan.gov>; Wednieski, Donna (DHHS) <WednieskiD@michigan.gov>; Willson, Jeffrey (DHHS) <WillsonJ1@michigan.gov>
Cc: Hessem, Amanda (DHHS) <HessemA@michigan.gov>
Subject: FW: Information regarding AVERSYS Laboratories

Do you have specific issues with Averhealth? If you do, please provide them to me as requested below. Thanks

---

From: Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Sent: Tuesday, September 22, 2020 10:25 AM
To: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>; Clore, Maureen (DHHS) <CloreM@michigan.gov>; Davis, Lisa (DHHS) <DavisL6@michigan.gov>; Keller, John (DHHS) <KellerJ2@michigan.gov>; Lemay, Jamie (DHHS) <LemayJ1@michigan.gov>; Mularz, Kara L. (DHHS) <MularzK@michigan.gov>; Parrott, Scott (DHHS) <ParrottS2@michigan.gov>; Savage, Jennifer (DHHS) <SavageJ1@michigan.gov>; Yohe, Matthew (DHHS) <YoheM@michigan.gov>
Cc: Cool, Savanah (DHHS) <CoolS@michigan.gov>; Sage, Stacy (DHHS) <SageS1@michigan.gov>
Subject: RE: Information regarding AVERSYS Laboratories

CSA has an upcoming meeting with Averhealth about a few issues surrounding their performance. If you have specific examples to add, please forward them to me and include the case number, name, details, etc.

From: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>

Sent: Tuesday, September 22, 2020 10:22 AM
To: Clore, Maureen (DHHS) <CloreM@michigan.gov>; Davis, Lisa (DHHS) <DavisL6@michigan.gov>; Keller, John (DHHS) <KellerJ2@michigan.gov>; Lemay, Jamie (DHHS) <LemayJ1@michigan.gov>; Lovell, Luther (DHHS) <LovellL3@michigan.gov>; Mularz, Kara L. (DHHS) <MularzK@michigan.gov>; Parrott, Scott (DHHS) <ParrottS2@michigan.gov>; Savage, Jennifer (DHHS) <SavageJ1@michigan.gov>; Yohe, Matthew (DHHS) <YoheM@michigan.gov>
Cc: Cool, Savanah (DHHS) <CoolS@michigan.gov>; Sage, Stacy (DHHS) <SageS1@michigan.gov>
Subject: FW: Information regarding AVERSYS Laboratories

Has anyone been noticed by their courts of this going around on a list serve about Aversys false positives?

From: Lafontaine, Joncie (DHHS) <LafontaineJ@michigan.gov>
Sent: Tuesday, September 22, 2020 8:23 AM
To: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>; Hessem, Amanda (DHHS) <HessemA@michigan.gov>
Subject: FW: Information regarding AVERSYS Laboratories

I don't see you on this email.

From: Garcia, Lisa (DHHS) <GarciaL2@michigan.gov>
Sent: Tuesday, September 22, 2020 8:19 AM
To: Lafontaine, Joncie (DHHS) <LafontaineJ@michigan.gov>
Subject: FW: Information regarding AVERSYS Laboratories

This was recently used to excuse one of our clients for her positive tests and close the case. I am not sure if you got this or not but this is not okay and it is interfering in all of our cases where there are positive tests.

Lisa Garcia,
Foster Care, Juvenile Justice and Ed Planner Supervisor
Grand Traverse, Leelanau, Kalkaska DHHS
701 S. Elmwood, Traverse City, MI 49684
231-929-0184

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From: Janet Kronk <jkronk@gtcountymi.gov>
Sent: Monday, September 21, 2020 3:34 PM
To: Menzel, Alexandra (DHHS) <MenzelA@michigan.gov>; Amelia Mayhew <AMayhew@cfs3l.org>; Amy Reed <areed@bethany.org>; Andrea Hagen <ahagen@hccsnet.org>; Bill Burdette <burdette@viewofthebaylawyer.com>; Brett Baird <bcbaird@charter.net>; Bridget Goss <bgoss@wellspringlutheran.com>; Chelsea Hill <CHill@bethany.org>; Cynthia Conlon <conlonlegal@gmail.com>; Darling, Brooks <abdarling@abdlawtc.com>; David Grunst <dgrunst@charter.net>; Dawn Smith <dmsmith@bethany.org>; Wednieski, Donna (DHHS) <WednieskiD@michigan.gov>; Garcia, Lisa (DHHS) <GarciaL2@michigan.gov>; Jacob Graff <graff41@hotmail.com>; Kathryn Waldron <KWaldron@cfs3l.org>; Kathy Morey <kmorey@grandtraverse.org>; Laura Garneau <laura@eastbaylegal.net>; Linda Mayhew <lmayhew@hccsnet.org>; Lisa Zipser <lzipser@ccwestmi.org>; Lori Schmeltzer <lori@schmeltzerlaw.com>; Marie Walker <mw@mariewalkerpllc.com>; Maura Brennan <mnbrennan3@gmail.com>; Heethuis, Megan (DHHS) <HeethuisM@michigan.gov>; Gubbins, Melinda (DHHS) <GubbinsM@michigan.gov>; Michael Horowitz <mike@mlhorowitz.com>; Michelle Bostic <Bostic@bosticlegal.com>; Michelle L. Brunner <mbrunner@bethany.org>; Mike Corcoran <mjc@michaeljcorcoranlaw.com>; Molly Hoefakker <mhoefakker@ccwestmi.org>; ReAnn Gorton <rgorton@gtcountymi.gov>; Culbertson, Sara (DHHS) <CulbertsonS@michigan.gov>; Sharon Becker <SBecker@hccsnet.org>; Jennifer Weber <jweber@grandtraverse.org>
Subject: Re: Information regarding AVERSYS Laboratories

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Attachment included this time!!

Judge Stanton has asked that I forward the attached document to you regarding recent concerns as to accuracy/false positive testing from Aversys.

Thank you for your attention to this information.

Janet Kronk

On Mon, Sep 21, 2020 at 3:22 PM Janet Kronk <jkronk@gtcountymi.gov> wrote:

> Judge Stanton has asked that I forward the attached document to you regarding recent concerns as to accuracy/false positive testing from Aversys.
>
> Thank you for your attention to this information.
>
> Janet Kronk

From:	Parks, Colin (DHHS)
To:	Williams, Douglas (DHHS); Miller, Kathy Ann (DHHS); Marner, Shelly J. (DHHS); Wrayno, Jennifer (DHHS); Lovell, Luther (DHHS); Doane, Amanda (DHHS)
Cc:	Marshall, Teresa (DHHS); Needham, Linda Sue (DHHS); Westergard, Brooke (DHHS); Strong, Janien (DHHS); Bladen, Stacie (DHHS)
Subject:	RE: Concerns with Averhealth Drug Screens
Date:	Thursday, September 17, 2020 2:25:55 PM

Thanks Doug.

I have shared these with Amanda Doane who will work with the counties to obtain case specific details and connect with Averhealth to address each concern. Teresa, can you provide Amanda and I with the case specific details so that we are able to follow up asap?

From: Williams, Douglas (DHHS) <WilliamsD11@michigan.gov>
Sent: Thursday, September 17, 2020 3:20 PM
To: Miller, Kathy Ann (DHHS) <MillerK11@michigan.gov>; Marner, Shelly J. (DHHS) <MarnerS@michigan.gov>; Wrayno, Jennifer (DHHS) <WraynoJ@michigan.gov>; Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Cc: Marshall, Teresa (DHHS) <MarshallT@michigan.gov>; Needham, Linda Sue (DHHS) <NeedhamL@michigan.gov>; Westergard, Brooke (DHHS) <WestergardB@michigan.gov>; Strong, Janien (DHHS) <StrongJ1@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Bladen, Stacie (DHHS) <BladenS@michigan.gov>
Subject: Concerns with Averhealth Drug Screens

From: Williams, Douglas (DHHS) <WilliamsD11@michigan.gov>
Sent: Thursday, September 17, 2020 3:01 PM
To: Westergard, Brooke (DHHS)
Cc: Strong, Janien (DHHS)
Subject: Re: Concerns with Averhealth Drug Screens
I wanted to share the message we received from Monroe County with all of you given the concerns about the reliability of Averhealth drug screens that have been raised by other court jurisdictions.

From: Westergard, Brooke (DHHS) <WestergardB@michigan.gov>
Sent: Thursday, September 17, 2020 2:43:00 PM
To: Williams, Douglas (DHHS) <WilliamsD11@michigan.gov>
Cc: Strong, Janien (DHHS) <StrongJ1@michigan.gov>
Subject: FW: Concerns with Averhealth Drug Screens

Thought you should be made aware of this.

Brooke

From: Marshall, Teresa (DHHS) <MarshallT@michigan.gov>
Sent: Thursday, September 17, 2020 2:36 PM
To: Westergard, Brooke (DHHS) <WestergardB@michigan.gov>; Strong, Janien (DHHS) <StrongJ1@michigan.gov>
Cc: Needham, Linda Sue (DHHS) <NeedhamL@michigan.gov>
Subject: Concerns with Averhealth Drug Screens

I wanted to bring your attention to an issue shared with us by the Monroe County Juvenile Court jurists. They voiced that they feel that the Averhealth drug screens are inaccurate and give false positives. It is at the point where they are telling parents to go get a second drug test to prove they are drug free. On more than one occasion this has caused the Court to "throw out" the Averhealth screens as being inaccurate and using the results of the parents private screens to make their decision.

One jurist (Cheryl Sweeney) has indicated that she has one case pending that is having this issue – where screens from Averhealth are coming back positive and private screens they take are negative. The jurists have indicated that they want to know what DHHS is going to do about what they have termed "the problems with Averhealth."

I have attempted to get case names for the affected cases. To date, they have not provided this information.

Teresa Marshall
Program Manager
Monroe County DHHS
903 South Telegraph, Suite A
Monroe, MI 48161
Ph: 734-243-7257
IPhone: 734-735-0877
Marshallt@michigan.gov

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From: Doane, Amanda (DHHS)
Sent: Mon, 28 Sep 2020 15:48:56 +0000
To: ddelagnes@averhealth.com
Subject: FW: Drug testing info

From: Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Sent: Friday, September 25, 2020 11:08 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: FW: Drug testing info

FYI Please see below. Courts throwing out Aver Health drug test results.

From: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>
Sent: Friday, September 25, 2020 11:05 AM
To: Lovell, Luther (DHHS) <LovellL3@michigan.gov>
Subject: FW: Drug testing info

This is specific information on the Grand Traverse and GTB courts dismissing positive screens due to the list serve that went out to our Judge.

Kristine Lagios, LMSW
Director Grand Traverse/Kalkaska/Leelanau DHHS
P. (231)929-2516 or (231)258-1208
Cell: (231)383-1546

"We do what is right by being present and connecting with Transparency, Dignity, and Respect."

MDHHS
Michigan Department of Health & Human Services

From: Lafontaine, Joncie (DHHS) <LafontaineJ@michigan.gov>
Sent: Friday, September 25, 2020 11:01 AM

To: Lagios, Kristine (DHHS) <LagiosK@michigan.gov>
Subject: Drug testing info

Kris- I reviewed her email and you should have all the information you requested.

From: Garcia, Lisa (DHHS) <GarciaL2@michigan.gov>
Sent: Thursday, September 24, 2020 4:28 PM
To: Heethuis, Megan (DHHS) <HeethuisM@michigan.gov>
Cc: Lafontaine, Joncie (DHHS) <LafontaineJ@michigan.gov>
Subject: Drug testing info

MCL 15.243(1)(a), case number MCL was testing positive for cocaine. She tested positive on 6/29/20, 6/30/20, 7/6/20 and 8/26/20. She denied that she had been using and when Katie went to Court the positive drug screens were not recognized as positive screens and were dismissed as being false positives. This occurred in Judge Stanton's Courtroom. The case was then dismissed from Court jurisdiction.

Katie just had a 2 hour court hearing in Tribal Court, MCL and MCL are the parents, case number MCL the court refused to admit any of the positive tests that occurred for [redacted] on 8/13/20, 9/4/20, 9/10/20 and 9/16/20. M tested positive on 8/20/20 and 9/18/20. All of the rest of the tests were no shows and the court would only admit into the record the missed tests due to the issue that Mr. Grunst raised at the court hearing regarding false positives. They then adjourned the court hearing for 3 weeks from now. All of this is due to the information that was sent out by Judge Stanton regarding the "false positive" cases down State.

Lisa Garcia,
Foster Care, Juvenile Justice and Ed Planner Supervisor
Grand Traverse, Leelanau, Kalkaska DHHS
701 S. Elmwood, Traverse City, MI 49684
231-929-0184

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Total Number of Redactions in Document: 7

Redaction Reasons by Page

Page	Reason	Description	Occurrences
2	MCL 15.243(1)(a)	(4)(a) Information of a personal nature if public disclosure of the information would constitute a clearly unwarranted invasion of an individual's privacy	7

Redaction Log

Redaction Reasons by Exemption

Reason	Description	Pages (Count)
MCL 15.243(1)(a)	(4)(a) Information of a personal nature if public disclosure of the information would constitute a clearly unwarranted invasion of an individual's privacy	2(7)

Fabry <jfabry@saulttribe.net>; Cheryl Hill <CHill@mqtco.org>; Langton, Lisa <langtonl@oakgov.com>; Mcnabb,Deborah <Deborah.mcnabb@kentcountymi.gov>; Feeney,Kathleen <kathleen.feeney@kentcountymi.gov>; Elizabeth Clement <ClementE@courts.mi.gov>; Megan Cavanagh <CavanaghM@courts.mi.gov>
Cc: Chang, Jooyeun (DHHS) <ChangJ4@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Rummel, Sandra (DHHS) <RummelS1@michigan.gov>
Subject: Urgent: Significant Development with AverHealth Drug Testing Errors

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Greetings:

I received a telephone call today from Dr. Sarah Riley, the former director of labs at AverHealth. If you will recall, Dr. Riley participated in the joint Zoom meeting with us and other representatives at AverHealth in October. Dr. Riley also participated in a call with AverHealth and members of the Parent and Children's Section of the Grand Rapids Bar Association in late October.

Dr. Riley informed me that last night she terminated her position as Lab Director with AverHealth because of her serious concerns that AverHealth has failed to follow standard testing procedures and is not compliant with the standards developed by the College of American Pathologists. AverHealth is accredited by the College of American Pathologists and emphasized that accreditation at our meeting in October. Dr. Riley advised me that she has filed a formal complaint against AverHealth with the College of American Pathologists.

The basis of her complaint, and the concern she raised with me, is that AverHealth does not follow the standard quality control procedures when conducting a test and reporting the results to the client. Dr. Riley stated that a test should be prepared, conducted, analyzed, and then re-tested under the required protocols to confirm the results before releasing the results. Individuals at AverHealth have shortened this process to only one test and analysis because they believe AverHealth has a good test record. Dr. Riley wanted to raise these concerns at our meeting but was directed not to do so.

Dr. Riley states that in certain circumstances the failed procedures can create a false positive, especially with cocaine, in approximately 30% of the tests. The frequency of a false positive could, in some instances, increase to 50%.

I considered Dr. Riley's statements and her tone during our conversation to be credible. I was not left with the impression that she was a disgruntled employee or had some "axe to grind." Dr. Riley gave me authority to share this information.

However, without further investigation, I cannot verify her claims. Nevertheless, this information is significant and calls into question the entire DHHS testing protocol under AverHealth.

I am providing this information to each of you because you have been involved in our

meetings with AverHealth. I believe this has to be investigated by DHHS, and the judges on this communication must be kept informed, and a plan for action and redress prepared

Best Regards,

TJ

T. J. Ackert
Judge
Kent County Circuit Court
Family Division and Specialized Business Docket
180 Ottawa Avenue NW, Ste. 10200B
Grand Rapids, MI 49503
616-632-5091

From: Doane, Amanda (DHHS)
Sent: Mon, 25 Oct 2021 13:46:29 +0000
To: O'Dell, Corina (DHHS)
Cc: Jordan, Mark (DHHS); Mularz, Kara L. (DHHS)
Subject: RE: Averhealth
Attachments: Averhealth Audit Report_Final.pdf, AVERHEALTH MEMO TO SCAO.pdf, Ingham County Court Opinion re Averhealth.pdf

Corina,

I am just back from a 5-week medical leave so that is why my response is not timely.

I would be happy to set up a meeting to discuss Averhealth. Let me give you a little background on the unfounded rumors that seem to still persist regarding Averhealth.

Almost a year ago a disgruntled Averhealth employee reached out directly to a judge in Michigan and told him that Averhealth was not following procedures and was reporting false results. As you can imagine this caused a huge crisis within MDHHS. We (MDHHS) hired an independent toxicologist who has a Ph.D. in toxicology to go to the lab in St. Louis and do a review of the lab and their procedures. A few months later we got a report from Dr. Wagner (the independent reviewer) that Averhealth was doing exactly what they were supposed to do and was giving the lab major kudos for their processes and procedures. There were only three minor suggestions he gave the lab and those suggestions were immediately implemented.

Averhealth is accredited by one of the most demanding bodies the College of Forensic Pathology – Forensic Drug Testing (CAP-FDT) and there are only about 30 labs in the country that can meet their strict accreditation requirements.

I have also included the Ingham County Opinion on Averhealth after these issues were brough forth in a case where the defense questioned Averhealth and their results.

Please let me know if you want me to schedule a Teams meeting to discuss.

Amanda

From: O'Dell, Corina (DHHS) <ODellC3@michigan.gov>
Sent: Friday, October 8, 2021 2:18 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Jordan, Mark (DHHS) <JordanM@michigan.gov>; Mularz, Kara L. (DHHS) <MularzK@michigan.gov>
Subject: Averhealth

Good Afternoon

It was brought to my attention by a client who completes various drug screens as part of their ongoing treatment. This includes averhealth through our department. Recently this individual tested positive but has not tested positive in many months for Averhealth nor their other drug screens. This individual is

adamant that they have not used and has continued to research and provide various evidence that leads us to be concerned as to whether or not they truly did test positive. That being said they were provided information from one of their other drug screening places about concerns with Averhealth and how individuals are suing Averhealth and the state of Michigan based on false positives. Amanda can you tell me if this is true? I know our local offices have had issues with Averhealth and have concerns, but I have even bigger concerns if we are getting false positives. Is there anything our local offices can do to best deal with these situations as they arise, especially if an individual has other drug screens such as urine screens within a day or so of the averhealth screen?

Corina O'Dell
Corina O'Dell
Ogemaw/Roscommon Co. DHHS
Children's Services Supervisor
989-329-7831

2/28/2021

[redacted]

Prepared by:
Jarrad R. Wagner, Ph.D., F-ABFT & Larry Broussard, Ph.D., D-ABCC

On Behalf of
Wagner Toxicology Associates

TABLE OF CONTENTS

Laboratory Audit Report

1. Executive Summary

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory site visit from January 19-20, 2021 at Averhealth Lab in St. Louis, Missouri. In general, the site visit was performed to confirm that the laboratory personnel were performing their laboratory work in accordance with their laboratory manual or standard operating procedure (SOP), and that the laboratory manual accurately reflects what is being done in the lab. The site visitors in this case also assessed if those practices were consistent with acceptable forensic laboratory practices. The laboratory director is Dr. Michele Glinn and she supervises a staff of appropriately educated and trained laboratory staff. A relatively small number of reports was audited during the visit, and the reporting process was observed. Following the visit, the team was made aware of specific concerns brought to the State of Michigan, Department of Health and Human Services through the judiciary. None of the items of concern were observed during the audit or are valid in the current laboratory practices. The team specifically did not audit the software related to submission of sample data or the software used to report, but they did observe the valid analytical data used for reporting. While some issues were identified and recommendations for improvements were made, the results reported by the laboratory can be scientifically supported and forensically defended in court. The Averhealth Lab team has indicated that they have implemented improvements to provide additional confidence to the State of Michigan, Department of Health and Human Services that the results reported are accurate and defensible. The team would be willing to revisit the laboratory and assess the implementation of their recommendations or review them through a virtual site visit.

2. Site Visit

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory audit January 19th and 20th, 2021 (Tuesday and Wednesday) at the Averhealth Lab located at 4709 LaGuardia, Suite 100, St. Louis, MO 63134. The laboratory director is Michelle Glinn, Ph.D., F-ABFT, and she hosted the audit team with the rest of the Averhealth Lab staff.

The site visit consisted of an inspection and data audit. Dr. Wagner conducts NLCP inspections and had also participated in CLIA and COLA accreditation audits. Dr. Broussard conducts NLCP inspections and also participates in CAP, CLIA and COLA inspections. The biographies of the site visitors are provided in Auditor Biographies.

The lab is accredited by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA), the State of New York, and the College of American Pathologists (CAP). It was inspected by CAP in February of 2020 and was given a glowing review: “The management team has done a great job at implementing and maintaining the CAP standards for accreditation. The SOP’s have been updated since the last onsite inspection and provide sufficient detail in all areas. The lab is well maintained and has

sufficient space for current operations and future growth. Bench staff are well trained and very knowledgeable in their duties."

The site visit was initiated by a tour on January 19th. The team focused on oral fluid specimens that were being processed for Michigan only. The team observed accessioning, screening, and confirmation of oral fluid specimens. The testing process has immunoassay screening, followed by confirmation of positives with liquid chromatography-tandem mass spectrometry (LC-MS/MS). Only analytes that have screened positive are reported, according to the information in Table 1. It is common practice in forensic laboratories to only report confirmation results that are associated with positive presumptive screening tests.

Table 1. Screening and confirmation for MI DHHS

Screen Drug	Screen Cutoff	Drug Class	Confirmation Analytes	Cutoff
Amphetamines	12.5 ng/mL	Amphetamines	Amphetamine	6.25 ng/mL
Methamphetamines	12.5 ng/mL	Amphetamines	MDA	6.25 ng/mL
		Amphetamines	MDEA	6.25 ng/mL
		Amphetamines	MDMA	6.25 ng/mL
		Amphetamines	Methamphetamine	6.25 ng/mL
		Amphetamines	Phentermine	6.25 ng/mL
Benzodiazepines	20 ng/mL	Benzodiazepines	Alprazolam	10 ng/mL
		Benzodiazepines	Clonazepam	10 ng/mL
		Benzodiazepines	Diazepam	10 ng/mL
		Benzodiazepines	Flunitrazepam	10 ng/mL
		Benzodiazepines	Flurazepam	10 ng/mL
		Benzodiazepines	Lorazepam	10 ng/mL
		Benzodiazepines	Midazolam	10 ng/mL
		Benzodiazepines	Nordiazepam	10 ng/mL
		Benzodiazepines	Oxazepam	10 ng/mL
		Benzodiazepines	Temazepam	10 ng/mL
Buprenorphine	5 ng/mL	Buprenorphine	Buprenorphine	2.5 ng/mL
		Buprenorphine	Norbuprenorphine	2.5 ng/mL
Cocaine	3.5 ng/mL	Cocaine	Benzoylecgonine	2 ng/mL
		Cocaine	Cocaine	2 ng/mL
Fentanyl	2 ng/mL	Fentanyl	Fentanyl	1 ng/mL
		Fentanyl	Norfentanyl	1 ng/mL
Opiates	7.5 ng/mL	Opiates	6-MAM	0.5
Oxycodone	10 ng/mL	Opiates	Codeine	3.75 ng/mL
		Opiates	Hydrocodone	3.75 ng/mL
		Opiates	Hydromorphone	3.75 ng/mL
		Opiates	Morphine	3.75 ng/mL
		Opiates	Noroxycodone	3.75 ng/mL
		Opiates	Nohydrocodone	3.75 ng/mL
		Opiates	Oxycodone	5 ng/mL
		Opiates	Oxymorphone	5 ng/mL

Screen Drug	Screen Cutoff	Drug Class	Confirmation Analytes	Cutoff
THC	1 ng/mL	THC	THC	.5 ng/mL
Tramadol	10 ng/mL	Tramadol	Tramadol	5 ng/mL

The accessioning personnel were competent and capable of assigning specimen testing without sample switches. They also performed the initial aliquot for oral fluid screening via immunoassay. All samples appear to be undergoing testing as indicated in the reporting.

If samples are negative, they are reported as such and they are stored for a short time prior to being discarded. If samples are positive in the immunoassay, the positive result is confirmed using LC-MS/MS according to Table 1, and the samples are stored for a longer duration than negative specimens in case a new analysis is requested.

We observed the preparation of a batch of confirmation samples, including standard oral fluid confirmations and some specialty analyses. We also observed a sample get aliquoted for GC/MS confirmation of ethanol. The team did not verify the GC/MS procedure or assess the method or results. This is not a common practice and it is unknown how ethanol detected in oral fluid results are related to blood alcohol concentration, but this will be followed up on in a separate report.

The personnel doing the LC-MS/MS sample preparation were competent. They used barcodes and identified the samples prior to pipetting. They used calibrated and verified pipettes, and they verified pipet performance on a weekly basis with relevant volumes.

The calibrators and quality control samples were made from separate lots and were made at the levels specified in the Standard Operating Procedure (SOP) “18- Oral Fluid Confirmation for the State of Michigan.” The instruments were loaded and unloaded with care to avoid sample switches and allow for reinjection (if needed). The laboratory employs an onsite maintenance person and the LC-MS/MS units are in excellent condition. Performance is verified on a daily basis and within each batch.

The laboratory is one of approximately 100 participating labs in the College of American Pathologists (CAP) Oral Fluid Proficiency Testing program. The laboratory receives 4 sets (A-D) per year consisting of 5 samples/set. Samples are analyzed by immunoassay screening and LC-MS/MS confirmation testing and results are reported to CAP. Results of each lab are compared to the expected results and the results obtained by all of the labs. If a laboratory reports a result outside of the acceptable limits (based on the mean of the values reported by all labs), it must investigate. The results for the 4 PT sets analyzed in 2020 were reviewed during the visit to the lab, and the laboratory received acceptable scores for each set, with appropriate investigation of results outside of acceptable limits, showing that there was no evidence of any systemic problems. The laboratory performed very well on their CAP Proficiency Specimens, with a 100% accuracy score in the last proficiency test set completed in November/December of 2020.

3. Areas of Concern

Immunoassay

In reviewing the revised immunoassay cutoffs for the State of Michigan, it was discovered that the targeted concentration was calculated as the neat value and not the dilute value as intended. Also, too many opiates were included in the calibrator, as there is cross reactivity with multiple analytes in the assay used. Overall, the cutoffs for the immunoassay were more sensitive than intended since the screens were implemented. As this did not result in any false negatives, the site visit team felt this could be easily corrected. The new, correct calibrator was prepared while the team was onsite and was to be validated for implementation.

The immunoassay quality control (QC) results were reviewed on an ongoing basis to determine if they performed acceptably. While the SOP called for the numerical QC result to be quantitatively evaluated, the QC results were evaluated on a qualitative basis, such that as long as expected negatives were negative and expected positives were positive, the assay was considered to be performing acceptably. The team advised that the laboratory should establish an acceptable range of numerical results and correct the calibration if the QCs fall outside of this range, before performing analysis of MI DHHS oral fluid specimens. In the opinion of the auditors this did not create any false positives or negatives in MI DHHS specimens, as the QC results were qualitatively accurate.

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

Prior to the site visit, 10 random reports and supporting data were provided to the audit team. The reports showed that some analytes were reported that were being flagged as outside identification criteria by the analytical software in use, MultiQuant. This raised a concern prior to arrival, but in and of itself wasn't necessarily an issue, since it was not known how MultiQuant was setup to flag outliers prior to the site visit.

After observation of the LC-MS/MS data processing, the team recommended that the LC-MS/MS identification criteria be clarified in the SOP. Basically, in order for an analyte to be confirmed as positive, it must fall within a specified time frame as compared to an analytical standard (retention time) and the ratio of the ion transitions that are being monitored must be within a specified tolerance to standards run in the batch. The data reviewers need to strictly follow the acceptance criteria that are included in the SOP, and it would make the review process easier if MultiQuant was setup with identical acceptance criteria to the SOP. Analytes that do not meet these requirements should not be reported. It is the understanding of the site visitors that Averhealth has now clearly defined the acceptance criteria for identification of analytes and is using them while reporting results.

The site visitors observed that the laboratory might change the linearity model or internal standard used for a specific analyte if the quality control (QC) values were outside the normal range. While this was written into the SOP, this practice would need to be supported by method validation data to be acceptable in an analytical laboratory.

4. Concerns Raised by the Judiciary

Subsequent to the visit, in the week of February 22, 2021, the team was made aware of allegations made by a former laboratory director through communication with judges and in her testimony at a trial. Specifically, the former laboratory director stated that the number of quality control (QC) specimens being run is insufficient and does not meet the 10% threshold that is required of CAP-accredited laboratories. There were an appropriate number of quality controls in the batches (>10%, 6 controls for every 50 specimens), both observed onsite in January and as described in the current SOP for Michigan Oral Fluid confirmations. In fact, the laboratory is currently using those 6 independent quality control specimens for batch sizes of forty (40). The inspectors observed that if the any of the controls failed in the LC-MS/MS, the specimens that required that QC were re-analyzed. The court was also concerned with a prior incident in which there were 13 "false positives" reported. Basically, in a prior batch the vials were put in the autosampler in the wrong location, causing 13 results to be associated with the wrong donors. Based on their discovery of this human error, Averhealth added independent sequence and vial checks that are currently in place, and in the opinion of the inspectors are sufficient to prevent a similar occurrence in the future. It was fortunate that the error was caught and the reports were corrected, and the multiple checks in place are appropriate to prevent this from reoccurring. The testimony of Dominique Delagnes that was provided to the inspectors was found to be accurate. There was an allegation that a false positive was reported, as a retest of the specimen was reported as negative. However, as explained in the testimony, the data in each analysis supported a positive finding with State of Michigan oral fluid cutoffs; however, the second result was reported based on an incorrect cutoff. Therefore, the data was analytically correct and reflected a positive result in both testing instances. Based on the rationale provided here, the inspectors did not observe any practices that support the allegations, and they were unsubstantiated.

5. Conclusions

The team feels that the items of concern expressed in this report do not indicate that the laboratory has reported any false negative or false positive results. The team is confident that the observed data was forensically and scientifically defensible in a court of law. Laboratory personnel were receptive to the team's recommendations to address the concerns discussed and indicated that they would begin this process immediately. The team recommends that the laboratory provide the updated procedures for review in order to ensure that the concerns expressed have been adequately addressed and the recommendations made have been appropriately understood and implemented.

6. Auditor Biographies

Dr. Larry Broussard

Larry A. Broussard, Ph.D., DABCC, is Professor Emeritus and former Department Head, Department of Clinical Laboratory Sciences, LSU Health Sciences Center (LSUHSC) in New Orleans, Louisiana. He earned a B.S. from Louisiana State University in Baton Rouge in 1970 and a Ph.D. in chemistry from the University of Texas at Austin in 1974. In 1977, following a

fellowship in the Department of Pathology at LSU Medical Center in New Orleans, he joined Medical Laboratory Associates (currently LabCorp) in Birmingham, Alabama, where he served in various positions including vice-president of technical services. He has also served as Laboratory Director of several laboratories including a SAMHSA-certified drug testing laboratory, the Toxicology Laboratory of the Orleans Parish Coroner's Office, and a regional clinical laboratory. He is board certified in clinical chemistry by the National Registry of Certified Chemists (NRCC) and the American Board of Clinical Chemistry (ABCC) and in toxicology by ABCC. Dr. Broussard received the Award for Outstanding Contributions in Education in 2004 from the American Association for Clinical Chemistry (AACC) and has received the School of Allied Health Professions Excellence in Teaching and the Allen Copping Excellence in Teaching Awards from LSUHSC in 2002 and 2005. He has more than 250 publications and presentations.

Dr. Broussard has been an active member of AACC for more than 40 years and served as President in 2008. He has served on 5 Annual Meeting Organizing Committees (AMOCs) including serving as the Chair of the 2001 AMOC. In addition to his service in AACC Dr. Broussard has served as a member of the Board of Directors of the National Academy of Clinical Biochemistry (NACB), ABCC, and NRCC and as President of NRCC. He has been selected as a fellow by NACB and the American Academy of Forensic Sciences (AAFS).

Dr. Broussard has been an inspector of SAMHSA-certified drug testing laboratories for more than 20 years and CAP-certified clinical laboratories for more than 30 years and continues to perform these inspections. He also serves as a technical specialist for Nuclear Regulatory Commission-required audits of drug-testing labs. In his capacity as Department Head he oversaw a Medical Technology Program that is certified by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). He retired from LSUHSC in 2016. His post-retirement activities include continued activity in forensic toxicology and laboratory medicine, 9 years of service as a member of the CAP Clinical Chemistry Committee, and currently serves on the AACC Nominations Committee. He also currently serves as Laboratory Director for 5 laboratories including 2 which perform pain management testing, 2 which perform molecular testing for respiratory pathogens, and one clinical regional reference laboratory.

Dr. Jarrad Wagner

Jarrad R. Wagner, Ph.D., F-ABFT is a Professor of Forensic Sciences at the Oklahoma State University Center for Health Sciences where he specializes in research and instruction in Forensic Toxicology and Chemistry. He is board certified as a Fellow of the American Board of Forensic Toxicology and an Associate Editor for the Journal of Analytical Toxicology. He works with tandem mass spectrometry (LC/MS/MS) and gas chromatography/mass spectrometry (GC/MS) instruments and supports forensic and clinical laboratories in method development, validation and training. He serves as a member of the AAFS/SOFT Drugs and Driving Committee, the AAFS/SOFT Oral Fluid committee, is a member of the National Safety Council Alcohol, Drugs and Impairment Division and is the Vice Chair of the Oklahoma State Board of Tests for Alcohol and Drug Influence. He is an inspector for National Laboratory Certification Program laboratories, which are Substance Abuse and Mental Health Services Administration (SAMHSA) certified.

Dr. Wagner is the laboratory director for several clinical laboratories, and supervises chemistry, toxicology and molecular biology activities. He provides expert witness in criminal and civil courts, reviewing analytical laboratory results and providing interpretation. Professor Wagner formerly served as a Chemist in the Hazardous Materials Response Unit of the FBI Laboratory, where he specialized in crime scene investigations involving hazardous materials throughout the world. Prior to the FBI, his law enforcement experience includes his time as a Forensic Scientist in the Toxicology section of the Orange County (CA) Sheriff-Coroner's office and his service as a Reserve Police Officer in the City of Irvine, CA. He is a former Assistant Professor of Chemistry and Director of the Forensic Sciences program at California State University, Fresno. Dr. Wagner earned a Ph.D. in Environmental Toxicology from the University of California at Irvine and undergraduate degrees in Biology and Chemistry.

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

ELIZABETH HERTEL
DIRECTOR

MEMORANDUM

DATE: March 15, 2021

TO: State Court Administrative Office

FROM: Demetrius Starling, State Bureau Administrator, Bureau of In-Home Services

SUBJECT: Averhealth Drug Testing Validity

In November 2020, the State Court Administrative Office (SCAO) received a letter that called into question the validity of drug testing services completed by the Michigan Department of Health and Human Services (MDHHS) contractor, Averhealth. Based on the concerns raised and the request of various courts, MDHHS contracted with Wagner Toxicology Associates for Jarrad Wagner, Ph.D., F-ABFT and Larry Broussard, Ph.D., D-ABCC, to complete a thorough assessment of the Averhealth laboratory in St. Louis, Missouri. This assessment included an audit of laboratory procedures, validation of the testing process, and an assessment to determine if Averhealth was meeting the College of Pathologists – Forensic Drug Testing accreditation standards. MDHHS requested the assessors review specific concerns related to testimony provided on February 19, 2021 by former Averhealth Lab Director, Dr. Sarah Riley, regarding employee practices and alleging that the testing practices used could have yielded false-positive drug test results.

Dr. Wagner and Dr. Broussard completed their assessment at the Averhealth laboratory and although there were recommendations made to strengthen testing procedures, the assessors concluded that the results reported by the laboratory are scientifically sound and forensically defensible in a court of law. There were no issues noted with the testing process, the validity of the results, or the qualifications of the lab and personnel. The team reviewed the specific concerns noted by the judiciary and found that none of these concerns were observed during the audit.

The executive summary report [Attachment 1] indicates there was no concern with bypassing the immunoassay screen as the chromatography test is a more sensitive and scientifically reliable test with more accurate results than immunoassay screening. If samples are positive in the immunoassay, the positive result is confirmed using the Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) testing for definitive results.

The assessors noted concerns about the relatively low cut off levels established by MDHHS. As a result, the Department has asked Dr. Wagner and Dr. Broussard to

conduct further assessments related to the established testing levels and offer recommendations regarding adjustments to the current levels. These assessments are currently being conducted and recommendations will be made to MDHHS no later than May 1, 2021. MDHHS is likely to receive these recommendations in March or early April.

The assessors also reviewed the testimony provided by Averhealth Chief Operating Officer, Ms. Dominique Delagnes and observed the analytical data used for reporting results. Specific to the contradicting testimony provided by the former laboratory director, Sarah Riley, and the current Chief Operating Officer, Dominique Delagnes, the assessors found the testimony given by Dominique Delagnes to be accurate based on their review and assessment. Assessors reviewed a report of a false positive with a later retest of the specimen being reported as negative. The team found that the testimony provided by Ms. Delagnes was accurate because the first test was completed using Michigan's cut off levels and the second test was reported based on an incorrect cutoff level; therefore, the data was analytically correct and reflected a positive result in both testing instances. Finally, the prior report of 13 "false positives" was noted as a human error and the assessors determined that Averhealth appropriately took actions to address this to prevent a similar occurrence in the future.

A meeting is scheduled on March 29th at 4:00 p.m. to provide an opportunity for jurists with interest to attend an overview presentation given by Dr. Wagner and Dr. Broussard. At this meeting, the doctors will explain the findings of their audit and take questions.

MDHHS remains committed to assuring accurate and reliable testing results are provided to clients, staff, and courts. We would like to be made aware of and have an opportunity to respond promptly to any concerns that arise. Please contact Demetrius Starling at StarlingD@michigan.gov with any questions or concerns.

STATE OF MICHIGAN
IN THE CIRCUIT COURT FOR THE COUNTY OF INGHAM
FAMILY DIVISION

In re MCL 15.243(1)(d)

FID No. MCL 15.243(1)(d)

HONORABLE LISA MCCORMICK

OPINION AND ORDER

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At a session of said Court held in the
City of Lansing, Ingham County, Michigan,
This 4th day of June, 2021.

PRESENT: HONORABLE LISA MCCORMICK, Circuit Court Judge

This matter comes before the Court on Respondent-Mother's motion to suppress drug screen results from Averhealth. The Court having reviewed the pleadings, heard testimony as well as argument, and being otherwise fully advised in the premises now **DENIES** Respondent-Mothers motion.

FINDINGS OF FACT

Petitioner admitted 12 Averhealth results for Respondent-Mother from a period of July 20, 2020 – January 21, 2021 during the Permanent Wardship Bench Trial.[1] During the course of the trial, Respondent-Mother questioned the accuracy of the Averhealth results.[2] On November 6, 2020, the Michigan State Court Administrative Office (SCAO) published a memorandum regarding concerns about the accuracy of drug test results provided by Averhealth. The

[1] Petitioner's Exhibit 2. The majority of the results were positive for Marijuana. All the results that were positive for marijuana were confirmed with the LC-MS/MS test and were over 2 ng/ml which is positive even under the increase to the cut off levels that went into effect on December 1, 2020.
[2] Respondent-Mother did not file a motion prior to the start of trial. The Court allowed Respondent-Mother to file its motion during the trial and argue the validity of the results.

memorandum set forth that an employee error led to 13 false positive test results in 2019. Averhealth sought to remedy the error through the adoption of new procedures that will provide greater oversight of the testing process. The memorandum went on to describe a subsequent false positive test result that was submitted in a court proceeding and allegations that Averhealth employee practices did not comply with the company's accreditation standards. When Department of Health and Human Services (DHHS) learned of the issue, they hired Wagner Toxicology Associates to conduct an independent investigation into the lab procedures and processes.

During the Permanent Wardship Bench Trial, witnesses were called to address concerns about the reliability of the Averhealth test results. The Court first heard testimony from Dominique Delagnes, Chief Operating Officer of Averhealth. Ms. Delagnes explained that the 13 false positive test results occurred because an employee skipped a slot when loading the samples into the testing apparatus causing each subsequently loaded sample to be sequentially off by one slot. The consequence of this error was that the test results for each sample after the skipped slot was associated with the wrong individual. Ms. Delagnes further testified that Averhealth addressed this issue by adding two more verification steps to the process in September or October of 2019 so that there are now three different individuals who check the sample sequence to prevent further error.

Ms. Delagnes explained how the false positive test result that was submitted in court and noted in the SCAO memo was not a false positive. Ms. Delagnes testified that they originally reported the test as negative. When asked to rerun the test several months later, the result was reported as positive. Ms. Delagnes explained the industry standard cutoff levels were higher than the custom Michigan cutoff levels and that Averhealth had performed an upgrade to their computer software, which caused the first test to apply the industry standard cutoffs instead of the Michigan cutoffs. Therefore, the test result was reported negative under the standard cutoff levels, but would

have reported positive had the lower Michigan cutoff levels been applied.[3] Beginning on December 1, 2020, Michigan has begun to apply the higher industry standard cutoff limits.

Finally, Ms. Delagnes testified that a former employee, Dr. Sarah Riley alleged that Averhealth was not complying with accreditation standards. Subsequent to those allegations, an investigation occurred by the Michigan State Police and several other individuals from different entities through Michigan.[4] Ms. Delagnes told this Court that the employee's claims were not substantiated and Averhealth's processes are valid, forensically defensible processes. DHHS also hired Wagner Toxicology Associates to conduct an independent investigation which was pending at the time of her testimony.

The Court next heard testimony from Dr. Sarah Riley, who testified as an expert in clinical lab science. Dr. Riley served as laboratory director for Averhealth from September 14, 2020 through November 3, 2020. Dr. Riley testified about her concern that Averhealth employees were not following standard operating procedures. She indicated that mass spectrometry is the "gold standard" method for testing in forensic toxicology. When using mass spectrometry, quality controls need to be included in every batch of specimens and the quality control samples should comprise ten percent of the batch. The quality control samples contain specific substances with specific intensities and are intended to ensure the accuracy of the results. Dr. Riley further testified that it was common practice at Averhealth for the analyst to continue to run the tests and report the results despite the quality control samples failing. Dr. Riley opined based on this practice and her observations that as much as 30% percent of the tests that Averhealth has done for Michigan could be false.

[3] Transcript of testimony of Dominique Delagnes, pgs. 24-26.
[4] Transcript of testimony of Dominique Delagnes, pgs. 14-15.

After Dr. Riley testified, DHHS received a report from an independent audit prepared by Dr. Jarrad Wagner and Dr. Larry Broussard on behalf of Wagner Toxicology Associates. Dr. Wagner testified as an expert in Forensic Science, Forensic Toxicology and Forensic Lab Science. Dr. Wagner indicated that his firm was hired by DHHS to conduct an audit of Averhealth. When Dr. Wagner was hired, he was not aware of the memo from SCAO dated November 6, 2020. Dr. Wagner and Dr. Broussard conducted a 2-day site visit on January 19-20, 2021. The purpose of the site visit was to confirm that personnel were conducting work in conformance with their standard operating procedure. As part of this site visit, a small number of reports were audited and he observed the laboratory process. There were some recommendations made but he opined the results reported were accurate and defensible.[5] In addition to his site visit and report, Dr. Wagner testified that he reviewed three laboratory results submitted by the Respondent-Mother. The collection dates were September 29, 2020, December 18, 2020. December 31, 2020.[6] It should be noted that the September 29, 2020 result was during Dr. Riley's tenure at Averhealth. He reviewed all related data from these results and confirmed the accuracy of all three results.

John Tarver from Quest Laboratories testified as an expert in Forensic Toxicology. Mr. Tarver's lab conducted two hair follicle tests submitted by Respondent-Mother. The hair specimen was collected on November 24, 2020 and February 8, 2021.[7] Both tests results were negative. Mr. Tanner did not review any of the Averhealth data or results.

ANALYSIS

[5] Averhealth Lab – Site Visit Report, Dated February 28, 2021. Prepared by Dr. Jarrad R. Wagner & Dr. Larry Broussard.

[6] Petitioner's Exhibit 5. The three results admitted as Petitioner's Exhibit 5 were admitted as part of the 12 results admitted as Petitioner's Exhibit 1.

[7] Respondent-Mother's Exhibits K and L. Respondent-Mother previously admitted the same results as Exhibit A and F.

Respondent-Mother argues there are three primary issues effecting the reliability of the Averhealth drug screens that warrant their suppression. First, in 2019, an employee error led to 13 false positive test results. Second, a subsequent drug screen from Averhealth was submitted in a court proceeding and found to be a false positive. Third, the testimony of Dr. Sarah Riley established that Averhealth was not following proper accreditation standards in their testing process. Respondent-Mother also argues the Petitioner failed to disclose the Averhealth investigation amounting to a *Brady* violation.

I. THE 2019 FALSE POSITIVE DRUG TEST RESULTS.

Whether the 2019 false positive test results create ground to suppress in the case at bar depends on whether the issues that led to the faulty results has since been rectified. The evidence before the Court shows that the batch of 13 false positives was the result of an employee error wherein the employee whom loaded the batches, inadvertently skipped a slot causing each subsequent sample loaded to be off by one slot. In September or October of 2019, two more quality control checks were added to the testing process. No subsequent issues of similar nature have been brought to the Court's attention. Dr. Wagner confirmed that the additional quality control checks were occurring when he completed his site visit. Based on the testimony and evidence received by the Court, the 2019 incident appears to be a singular event that has since been rectified through the implementation of additional quality control checks. The test results in this case were provided after the two additional quality control checks were put into place and there is nothing to indicate the 2019 incident affected any of Respondent-Mother's results.

II. THE SUBSEQUENT FALSE POSITIVE RESULT THAT WAS SUBMITTED DURING A COURT PROCEEDING.

The discovery of the subsequent false positive test has created an issue regarding the reliability of Averhealth test results. However, the evidence before the Court shows the result was

not a false positive. Instead, the evidence shows that the result reported was negative, using cutoff levels that were not standard in Michigan at the time. The Averhealth computer system caused the test to be administered under the higher industry standard cutoff levels. The subsequent retest reported positive when using Michigan cut-off levels. Thus, the issue was not the accuracy or the reliability of the results, but the cutoff levels applied to the test.

III. TESTIMONY REGARDING AVERHEALTH'S TESTING PROCESS.

Dr. Sarah Riley testified that Averhealth employees were not following standard operating procedures. Alternatively, Ms. Delagnes characterized Dr. Riley as a disgruntled employee whose claims were unsubstantiated. Dr. Riley testified how she discovered that Averhealth employees were continuing to report the results of patient samples despite the quality control samples failing. She testified that when she brought those concerns to the attention of Averhealth management, she was asked not to change anything and advised that Averhealth has contractual time constraints to report the data. Dr. Riley further testified that there were test results that she did not approve because she believed them to be inaccurate, but that she was unable to personally review every sample. When asked whether she believed the results of the tests done for the State of Michigan were erroneous, Dr. Riley indicated that she has significant concerns they were inaccurate and opined that as much as 30% of the test results could be false. However, she failed to provide any specific examples or provide the court with any examples from any results admitted in this matter.

Ms. Delagnes testified the allegations noted in the November 6, 2020 SCAO memo regarding Averhealth employees not complying with the company's accreditation standards were made by Dr. Riley who worked at Averhealth for approximately six weeks. Ms. Delagnes further testified that Averhealth employees followed standard operating procedures on a consistent basis. She informed the Court that DHHS, the Michigan State Police, and an individual named Paul

Kerry have conducted an independent investigation and concluded that Averhealth's processes are valid and forensically defensible.

Dr. Wagner provided an independent review of Averhealth's procedures. He was not aware of the allegations when he went to Averhealth for the site visit. He only learned of the allegations in between his site visit and his report being finalized. He had nothing to gain and did a thorough, complete review of the testing process. In addition to his findings, he randomly selected three results from this matter. He reviewed the data that supported the positive results and determined the results are reliable and accurate.

Mr. Tarver provided the Court with two hair follicle testing results. These results provide a 90-day look back as an indicator to determine use. Both results were negative. However, Mr. Tarver conceded that if a hair follicle test is negative, it is possible to have positive results from a different screen during the 90-day time period. This was confirmed by Eugene Schwilke, an expert in toxicology employed by Averhealth.[8] He testified the results may be different, even if taken at the same time, depending on whether the test is oral, urine or hair. The factors include the timing of the drug exposure, the amount of use and the sensitivity as well as the methodology used.

It is the Court's duty as the trier of fact to determine the credibility of the witnesses. The Court has heard the testimony of Ms. Delagnes, Dr. Riley, Dr. Wagner and Mr. Tarver regarding the reliability of the results.[9] Dr. Wagner conducted an independent review of Averhealth's laboratory process and testing. In addition to his independent site audit, he reviewed three results

[8] Eugene Schwilke explained the differences between Immunonassy and confirmation tests and the different types of tests including oral, urine and hair follicle tests. He did not testify regarding the accuracy or reliability of the results.

[9] Sarah Doane also testified. She is an employee of DHHS. She did not provide any testimony as to the validity of the Averhealth results. Eugene Schwilke did not testify as to the accuracy of the Averhealth results in this matter.

from this matter. He found the results accurate. The Court finds Dr. Wagner's testimony to be credible and reliable. Dr. Riley's testimony was speculative and did not provide the Court with any specific examples. Mr. Tarver indicated that it was possible to have a positive result 90 days before a hair follicle test. Therefore, the Court finds that the results admitted from Averhealth are reliable and denies suppression of Respondent-Mother's test results.

BRADY ALLEGATION

Respondent-Mother claims that the Petitioner failed to disclose information about investigations of Averhealth in violation of *Brady* v *Maryland* 373 US 83 (1963).[10] The Court of Appeals in an unpublished opinion did not apply the Brady requirements in child protective proceedings. *In re Condron,* unpublished opinion per curiam of the Court of Appeals, decided August 20, 2020 (Docket No. 351240).[11] However, even if *Brady* did apply, the Court of Appeals adopted a four-factor Brady test. *People* v *Chenault*, 495 Mich 142, 151 (2014). The moving party must prove 1) that the state possessed evidence favorable to the defendant 2) that the evidence could not be obtained with any reasonable diligence 3) that the prosecution suppressed favorable evidence and 4) that the evidence if disclosed to the accused, a reasonable probability exists that would change the outcome of the proceedings. *Id.* at 151. There was no testimony that the prosecutor suppressed evidence or that the prosecutor suppressed any information specifically as to any of the results in this matter. There was also no testimony that DHHS withheld any information regarding these specific test results. Even assuming DHHS had the information about the Averhealth allegations, the evidence presented is not favorable to the

[10] Respondent-Mother's Brief in Support of Motion to Suppress Averhealth Drug Test Results.
[11] *In re Condron* was remanded to the trial court on other grounds. After the remand and a ruling from the trial court, the case was appealed *In re Condron*, unpublished opinion per curiam of the Court of Appeals, decided January 21, 2021 (Docket No. 351240). The issue of *Brady* in child protective proceedings was not addressed in the subsequent appeal.

Respondent-Mother. The evidence shows the Averhealth results are reliable and defensible in court. Even if the Court were to apply *Brady* to this case, the court does not find a *Brady* violation.

THEREFORE, IT IS HEREBY ORDERED that Respondent Mother's motion to suppress Averhealth results is **DENIED**.

6/4/2021
DATE

HONORABLE LISA MCCORMICK

Redaction Log

Total Number of Redactions in Document: 2

Redaction Reasons by Page

Page	Reason	Description	Occurrences
14	MCL 15.243(1)(d)	(6) Records or information specifically described and exempted from disclosure by statute.	2

Redaction Log

Redaction Reasons by Exemption

Reason	Description	Pages (Count)
MCL 15.243(1)(d)	(6) Records or information specifically described and exempted from disclosure by statute.	14(2)

Michigan Supreme Court
State Court Administrative Office
Michigan Hall of Justice
P.O. Box 30048
Lansing, Michigan 48909
517-373-0128

Thomas P. Boyd
State Court Administrator

M E M O R A N D U M

DATE: November 6, 2020

TO: Family Court Judges

FROM: Thomas P. Boyd

SUBJECT: Concerns Raised Regarding Averhealth Drug Test Results

---

Concerns have been brought to our attention regarding the accuracy of drug testing results provided by Averhealth, the company under contract with the Michigan Department of Health and Human Services (MDHHS) to provide substance use testing services to families involved in the child welfare system.

In 2019, an Averhealth employee error led to 13 false positive test results. This was described as a one-time employee error, and was remedied by Averhealth providing written documentation to each client to explain the error, and adopting new procedures to provide more oversight of the testing processes. Recently, there was another false positive drug test that was submitted in a court proceeding. In addition, we have been informed that allegations have been raised regarding Averhealth employee practices not complying with the company's accreditation standards. MDHHS is currently investigating these allegations. We will provide additional information as it becomes available.

STATE OF MICHIGAN
MIDLAND COUNTY PROBATE COURT
42ND CIRCUIT COURT – FAMILY DIVISION

At a session of Court held in the City of Midland,
Midland County
On the 10th day of November 2020

PRESENT: Honorable Dorene S. Allen
Presiding Probate and Family Court Judge

BLANKET ORDER REGARDING SUBSTANCE USE TESTING
FOR MIDLAND COUNTY CHILD PROTECTION CASES

This Court having been involved in the analysis of the quality and reliability of Aver Health a/k/a Aversys and their substance use testing, hereby orders that from this date forward an alternative lab will be used for child protection cases through this Court.

In 2019, this Court was apprised of a false positive result in a pending child protection action. The Court heard sworn testimony from an Aver Health official and it was represented that quality controls were put into place to ensure that this would never occur again. Despite that, currently there are significant questions regarding the reliability of Aver Health.

There is a requirement that parents and parties to these child protection actions be confident that the laboratory results of the substance use testing are accurate. There must to be security for the Court as well. Decisions are made as to the welfare of children in these proceedings based upon all the facts. The Court relies upon the accuracy of information.

On November 6, 2020, the Michigan Supreme Court State Administrative Office issued this Memorandum:

> Concerns have been brought to our attention regarding the accuracy of drug testing results provided by Averhealth, the company under contract with the Michigan Department of Health and Human Services (MDHHS) to provide substance use testing services to families involved in the child welfare system.
>
> In 2019, an Averhealth employee error led to 13 false positive test results. This was described as a one-time employee error, and was remedied by Averhealth providing written documentation to each client to explain the error, and adopting new procedures to provide more oversight of the testing processes. Recently, there was another false positive drug test that was submitted in a court proceeding. In addition, we have been informed that allegations have been raised regarding Averhealth employee practices not complying with the company's accreditation standards. MDHHS is currently investigating these allegations. We will provide additional information as it becomes available.

This Court therefore orders that substance abuse testing be conducted by an alternate laboratory to be selected by this Court. Inasmuch as Aver Health was chosen by Michigan Department of Health and Human Services all expenses for such alternate testing shall be the responsibility of the Michigan Department of Health and Human Services.

This order shall remain in effect until such time as an alternate testing laboratory is available through the Michigan Department of Health and Human Services.

November 10, 2020

Hon. Dorene S. Allen
Presiding Probate and Family Court Judge

STATE OF MICHIGAN

31ST CIRCUIT COURT FOR THE COUNTY OF ST. CLAIR
FAMILY DIVISION

At a session of said Court, held at the County Building, in the City of Port Huron, said County and State, on the 16th day of November, 2020.

PRESENT: HON. ELWOOD L. BROWN
Probate/Family Division Judge

BLANKET ORDER REGARDING SUBSTANCE USE TESTING FOR ST. CLAIR COUNTY CHILD PROTECTION CASES

This Court having been involved in the analysis of the quality and reliability of Aver Health a/k/a Aversys and their substance use testing, hereby order that from this date forward an alternative lab will be used for child protection cases through this Court.

Since 2019, this Court was apprised of a false positive result in pending child protection actions around the state. Currently there are significant questions regarding the reliability of Aver Health.

There is a requirement that parents and parties to these child protection actions be confident that the laboratory results of the substance use testing are accurate. There must also be security for the Court as well. Decisions are made as to the welfare of children in these proceedings based upon all the facts. The Court relies upon the accuracy of information.

On November 6, 2020, the Michigan Supreme Court State Administrative Office issued this Memorandum:

> Concerns have been brought to our attention regarding the accuracy of drug testing results provided by Averhealth providing written documentation to each client to explain the error, and adopting new procedures to provide more oversight of the testing processes. Recently, there was another false positive

drug test that was submitted in a court proceeding. In addition, we have been informed that allegations have been raised regarding Averhealth employee practices not complying with the company's accreditation standards. MDHHS is currently investigating these allegations. We will provide additional information as it becomes available.

This Court therefore orders that substance abuse testing in child protective cases be conducted by a laboratory other than Aver Health. Inasmuch as Aver Health was chosen by Michigan Department of Health and Human Services all expenses for such alternate testing shall be the responsibility of the Michigan Department of Health and Human Services.

This order shall remain in effect until such time as an alternate testing laboratory is available through the Michigan Department of Health and Human Services.

November 16, 2020

Hon. Elwood L. Brown P-30069
Probate/Family Division Judge

Ex. 151

From: Starling, Demetrius (DHHS)
Sent: Monday, November 16, 2020 3:11 PM
To: Reinke, Jamie (DHHS); Walbecq, Deborah (DHHS)
Subject: FW: SC Court

FYI, more to come.

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Monday, November 16, 2020 3:08 PM
To: Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Cc: Marner, Shelly J. (DHHS) <MarnerS@michigan.gov>
Subject: RE: SC Court

Hi Demetrius,

Thanks for the heads-up. Unfortunately, this may be occurring with many of our courts in the coming days. Hopefully this is for the short-term, but time will tell. We have developed a communication and it is with CSA right now for review. My hope is to have it sent out soon to provide some field guidance shortly. Don't hesitate to email/call if there is anything you need before that guidance goes out. Take care!

From: Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Sent: Monday, November 16, 2020 2:56 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Marner, Shelly J. (DHHS) <MarnerS@michigan.gov>
Subject: SC Court

Good afternoon Colin, I hope that all is well.

Just an FYI, I received a call this afternoon from Mike McMillan, Court Administrator in St. Clair regarding Averhealth. He informed me that Referee Sam Lord convened a meeting with the judges this morning and they have all decided that they will no longer accept any screen information from Averhealth. Referee Lord reportedly stated this on the record on a case this morning and stated that MDHHS will refer the parents to a new agency for drug screens. Mike went on to state that the judges will add specific language to the orders going forward regarding their refusal to accept Averhealth's results, and that we are being ordered to contract with a different agency.

Demetrius Starling
Director
St. Clair/Sanilac County
Department of Health and Human Services
810-966-2187 (desk – St. Clair)
810-648-3863(desk – Sanilac)
810-493-0770 (cell)
Follow us on Twitter

Ex. 152

From: Doane, Amanda (DHHS)
Sent: Friday, December 4, 2020 11:49 AM
To: Schlaufman, Jody L . (DHHS);Parks, Colin (DHHS);Eurich, John D. (DHHS)
Subject: RE: Oscoda County Court Drug Screening Order

What are you doing for non-court cases?

From: Schlaufman, Jody L . (DHHS) <SchlaufmanJ@michigan.gov>
Sent: Friday, December 4, 2020 12:09 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Eurich, John D. (DHHS) <EurichJ@michigan.gov>
Subject: Oscoda County Court Drug Screening Order

Hello,

I am contacting you regarding the drug screening process for Oscoda Co DHHS. We had received notice from the Oscoda County Court previously that they would not be accepting drug screening results from Averhealth. We had worked to identify a potential alternate drug testing provider for Oscoda. Oscoda County Court has issued an order that substance abuse testing be conducted by an alternate laboratory to be selected by the Court. Forensic Fluids was identified as an acceptable alternate provider.
We have communicated with Forensic Fluids and secured them as a provider. We prepared to proceed with them as an alternate drug screening provider. We have followed the protocol outlined in the meeting and in the Power Point.

Please let me know if there are questions. I appreciate your assistance with this.

Thank you,

Jody

Jody Schlaufman
Acting Director
Crawford, Oscoda and Otsego Counties
931 S Otsego Ave
Gaylord, MI 49735
989-590-2825
Fax 989-732-8715

From: Starling, Demetrius (DHHS)
To: Machen, Shayne (DHHS)
Subject: FW: Letter to SCAO and State Court Judges re Averhealth
Date: Monday, December 13, 2021 12:50:00 PM
Attachments: image001.png

Am I sending this out?

From: Martin, Danielle (DHHS) <MartinD28@michigan.gov>
Sent: Monday, December 13, 2021 10:17 AM
To: Machen, Shayne (DHHS) <MachenS@michigan.gov>; Lovell, Luther (DHHS) <LovellL3@michigan.gov>; Marner, Shelly J. (DHHS) <MarnerS@michigan.gov>; Williams, Douglas (DHHS) <WilliamsD11@michigan.gov>; Wrayno, Jennifer (DHHS) <WraynoJ@michigan.gov>; Campau, Wendy (DHHS) <CampauW@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>
Cc: Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Subject: RE: Letter to SCAO and State Court Judges re Averhealth

Thank you for the update and the opportunity to review. I suggested only one change below in red, just because these are such tenuous situations for the field.

Danielle Martin
MDHHS Business Service Center #3
Phone: 231-492-7939
800 Water Tower Rd
Big Rapids, MI 49307

DHHS Footer

Confidentiality Notice:
This e-mail message, including any attachments, may be privileged and confidential, protected from disclosure under the Child Protection Law (Public Act 238 of 1975), and is intended only for use of the individual or entity to which it is addressed. If the reader of this message is not the intended recipient or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited, and may be subject to civil and/or criminal penalties. If you have received this communication in error, please notify the sender immediately, delete all copies from your computer and destroy the original message. No portion of this transmission may be released to the media without prior approval.

From: Machen, Shayne (DHHS) <MachenS@michigan.gov>
Sent: Monday, December 13, 2021 10:03 AM
To: Lovell, Luther (DHHS) <LovellL3@michigan.gov>; Marner, Shelly J. (DHHS) <MarnerS@michigan.gov>; Martin, Danielle (DHHS) <MartinD28@michigan.gov>; Williams, Douglas (DHHS) <WilliamsD11@michigan.gov>; Wrayno, Jennifer (DHHS) <WraynoJ@michigan.gov>; Campau, Wendy (DHHS) <CampauW@michigan.gov>; Click, Tim (DHHS) <ClickT@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Willis, Rachel (DHHS) <WillisR4@michigan.gov>

Cc: Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Subject: FW: Letter to SCAO and State Court Judges re Averhealth

Good morning,

On Thursday morning, a few of us attended the Child Welfare Leadership Workgroup. This is a workgroup comprised of state court judges, a tribal judge, and SCAO staff. At this meeting, there was a lot of discussion about Averhealth and judges expressed frustration over past false positives and newer concerns about (allegedly) inconsistent responses. Obviously, we want them to direct concerns to the county and we reinforced working with local leadership, but its clear that not all of them will take that approach. In response to their concerns, we gave them Rachel's contact information and asked them to direct Averhealth concerns to her (as opposed to the judges listserv) so that we could follow-up on each of those concerns. The plan is for Rachel to loop in Jen Warner and the BSC director for that area and assist with resolving any concerns. The purpose for looping in Jen Warner is so that she can advise about whether we can/should use the Averhealth contract terms to address those concerns. In response, the Judges asked for a letter to share with other state court judges communicating her contact information and our willingness to look into each concern. Below is the paragraph I suggest sending. Please offer any edits or suggestions. Once approved, we'll put it on letterhead and I'll ask Jen Warner to send it over to SCAO.

To Michigan State Court Judges,

On December 9, 2021, the Child Welfare Leadership Workgroup discussed Averhealth drug testing services. During this meeting, individual jurists expressed frustration with the services provided by Averhealth in local child welfare cases. While we standby the fidelity of Averhealth services, in response to individual jurist concerns, the Department committed to follow up on specific concerns about Averhealth services. As part of this commitment, we encourage jurists to work with local MDHHS leadership to resolve concerns. However, if jurists wish to seek CSA involvement subsequent to local follow-up, please do not hesitate to contact Out of Home Services Bureau Director, Rachel Willis at WillisR4@michigan.gov. Director Willis will coordinate the Department's response and follow up with jurists once our review is complete.

Please know that we are committed to providing high quality, reliable drug testing services. We will continue to be responsive to judicial concerns as we greatly value this collaboration and our joint efforts to meet the needs of Michigan families.

Very Sincerely,

Demetrius Starling

Shayne Machen, Esq.
Special Advisor to the Children's Services Agency Director
Michigan Department of Health and Human Services
Cell | 231-655-9857
Email | MachenS@Michigan.gov

Ex. 154-A

STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

ROBERT GORDON
DIRECTOR

M E M O R A N D U M

DATE: November 13, 2020

TO: Judge Thomas P. Boyd, State Court Administrator,
Family Court Judges, Tribal Court Judges, and involved stakeholders

FROM: JooYeun Chang, Executive Director, Children's Services Agency

SUBJECT: Averhealth Testing

Thank you for sharing with MDHHS your concerns regarding Averhealth, our statewide substance use screening provider. We recognize the seriousness of these concerns and their potential impact on cases before the court. We share with you a commitment to have accurate and reliable testing results and information upon which to make critical decisions. We recognize the importance of valid and reliable testing results on the court's ability to issue fair and defensible decisions and orders, and how critical those decisions are to the children and families we serve. We will thoroughly assess and resolve the concerns raised to the satisfaction of our court partners, appointed attorneys, field staff, and parents.

On November 6, 2020, Judge Boyd sent a memo to family court judges regarding Averhealth drug test results. MDHHS immediately followed up on the concerns Judge Boyd raised in the memo. One of the concerns cited was whether the testing process used by Averhealth met accreditation standards. MDHHS consulted with staff doctors at the MDHHS Chemistry and Toxicology Division and MDHHS Infectious Disease Division. We confirmed that Averhealth's testing process, specifically the use of chromatography testing (and not immunoassay) was appropriate. This determination was based on chromatography being a superior testing process. Chromatography is a confirmation test that, when used, dismisses the need to use immunoassay. Chromatography is more accurate and zeroes in on compounds in a manner immunoassay cannot.

Averhealth, on its own initiative, contacted the Michigan State Police drug lab to conduct an independent assessment of its testing protocol to determine whether it meets accreditation standards. A report will be available soon that Averhealth will share.

We also will conduct an independent assessment. Today, MDHHS contacted an independent forensic toxicology consultant, Paul Cary, retired MSP, to request independent verification that Averhealth's testing meets accreditation standards. We will share the results as soon as they are available.

In the time it takes us to resolve these concerns, if a court is not confident in the Averhealth tests, the court may utilize sample collection and testing through another local vendor and MDHHS will arrange to pay for the alternative testing. Options for alternative vendors may be limited in certain areas of the state; and we are working quickly to provide guidance to field staff on those options and payment procedures.

I continue to appreciate your partnership and patience as we work through these issues.

Michigan Department of Health & Human Services

Children's Services Agency

Communication Issuance

20-145

Subject/Title	Field Communication – Court Requested Substance Use Testing
Type	☐Informational Memorandum ☒Program Instruction ☐Policy Guide
Issuance Date Obsolete Date	11/20/20 N/A
Contact Name Email Phone	Colin Parks ParksC@michigan.gov 517-388-5125
Due Date Due to	N/A N/A
Distribution	☒ CSA Central Office Managers/Staff ☒ MDHHS BSC and County Directors ☒ MDHHS Juvenile Justice Managers/Staff ☒ MDHHS Child Welfare Managers/Staff ☒ Native American Tribes ☒ Office of Workforce Development and Training ☒ Private Agency Child Welfare Managers/Staff ☐ Private Residential Abuse/Neglect Managers/Staff ☐ Private Residential Juvenile Justice Managers/Staff ☐ Other:

The validity and reliability of substance use testing is critical to informing decisions in child welfare. Michigan Department of Health and Human Services (MDHHS) is working quickly to thoroughly review and resolve concerns raised about Averhealth and strengthen testing reliability overall by changing testing cutoff levels effective November 30, 2020. While we resolve concerns and work to improve reliability of testing results, Averhealth may continue to be used for substance use testing. Alternatively, until further notice, staff may also access other local providers for testing, if necessary.

Court Consultation for Other Substance Use Providers

At the request of a court or other party involved in a case, it may become necessary for MDHHS and private agency providers to seek an alternative provider, other than Averhealth, for substance use testing. MDHHS may accommodate these court requests to use an alternate vendor without a court order.

Please note that utilization of local vendors, and the laboratories they use, may result in variation of testing procedures (oral, urine and other), court testimony, costs, and testing cut-off levels. Alternate testing providers *must follow/utilize the established testing levels of the College of American Pathologists – Forensic Drug Testing (CAP-FDT) for all oral substance use screening.*

Substance Use Testing Liaison

Each county/district office and private agency provider has established a substance use testing liaison to assist with the substance use contract service. The liaison is responsible for:

- Identifying local substance use providers.
- Working with local courts to identify/discuss their substance use testing needs.
- Using the attached substance use provider tracking spreadsheet.

Substance use testing liaisons will receive a meeting notice from Amanda Doane by Monday, November 23, 2020, to discuss these steps and tracking requirements in greater detail and allow an opportunity for questions to be addressed.

Payment and Tracking Process for Other Substance Use Providers
If another substance use screening provider is used, services must be paid using the paid case service process in MiSACWIS (please review the attached job aid). Child welfare caseworkers should verify that the provider is registered in SIGMA, enrolled in Bridges, and shows as an active medical services provider in MiSACWIS. Ensure that the case service and paid service authorizations are approved prior to case closure. The Federal Compliance Division (FCD) will be monitoring use of these funds to ensure that Business Service Center (BSC) and county directors are aware of county usage. Questions regarding this process should be sent to the FCD mailbox: MDHHS-FederalComplianceDivision@michigan.gov.

Testing Levels
Effective November 30, 2020, the substance use cut off levels used by Averhealth will be changed to meet the College of American Pathologists - Forensic Drug Testing levels (CAP-FDT) for all oral screen testing. CAP-FDT levels are scientifically valid, forensically defensible, and are designed to ensure the reliability of testing results. These cut off levels will also reduce the probability of retesting variance (please review the attached Averhealth communication). MDHHS child welfare, private agency, tribal staff and the courts will be provided training from Averhealth that will address this change.

From: Parks, Colin (DHHS)
To: Jason Herzog
Cc: Dominique Delagnes; Doane, Amanda (DHHS)
Subject: RE: Urgent: Significant Development with AverHealth Drug Testing Errors
Date: Thursday, November 5, 2020 3:28:48 PM

Too funny. Sarah Riley it is.

From: Jason Herzog <jherzog@averhealth.com>
Sent: Thursday, November 5, 2020 4:28 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Dominique Delagnes <ddelagnes@averhealth.com>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Urgent: Significant Development with AverHealth Drug Testing Errors

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

She is, and maybe I'm being petty, but I don't think she merits the title.

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

> On Nov 5, 2020, at 2:24 PM, Parks, Colin (DHHS) <ParksC@michigan.gov> wrote:
>
> She is not a doctor?
>
> ---
>
> **From:** Jason Herzog <jherzog@averhealth.com>
> **Sent:** Thursday, November 5, 2020 4:04 PM
> **To:** Dominique Delagnes <ddelagnes@averhealth.com>
> **Cc:** Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
> **Subject:** Re: Urgent: Significant Development with AverHealth Drug Testing Errors
>
> **CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov**
>
> Can you also change Dr. Riley to Sarah Riley?

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

On Nov 5, 2020, at 2:03 PM, Dominique Delagnes <ddelagnes@averhealth.com> wrote:

Good afternoon Colin,

Thank you for pulling this together. See an edit below.

Thanks,

Dominique

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Thursday, November 5, 2020 3:43 PM
To: Dominique Delagnes <ddelagnes@averhealth.com>; Jason Herzog <jherzog@averhealth.com>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Urgent: Significant Development with AverHealth Drug Testing Errors

EXTERNAL: This email originated from outside averhealth. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

I have modified the summary a bit. Could Averhealth please review for accuracy and respond asap? Thanks!

Please find below a brief follow-up to the concerns raised by Judge Ackert, regarding the direct to chromatography method used by Averhealth. We are working with Averhealth in preparing additional information- which can be shared with courts, private agency partners and others, which we will send before cob tomorrow.

One point to make clear; the process that Dr. Riley and Judge Ackert have brought to our attention is used by Averhealth as a direct result of the low testing levels they are contracted to follow. *It is because these levels are so low, below the immunoassay cutoff established and validated by the reagent manufacturer, that Averhealth does not use immunoassay testing*

for an initial screen. However—Averhealth does use the chromatography method, which is a superior testing process.

Following our consultation with Averhealth, our office is confident that the process for testing and retesting meets, or exceeds contract requirements and industry standards.

- Standard industry practice is to first screen a sample using an immunoassay method, which provides a qualitative result, and then use a chromatography method to generate a definitive result to confirm the initial screen.
- It is also standard industry practice to go direct to chromatography when immunoassay is not possible.
- Chromatography is superior to immunoassay.
- There are no immunoassay reagents designed and validated to conduct an immunoassay screen at the cutoff levels specified by the MDHHS agreement.
- Because immunoassay reagents cannot accurately test at the current MDHHS cutoff levels, Averhealth tests all MDHHS samples using the superior chromatography method.
- The chromatography method, including quality control and analytical review processes, have been inspected by multiple PhD Toxicologists on behalf of CAP-FDT and others.
- All inspections have resulted in positive reports.
- Averhealth is preparing a summary of all inspections and the inspection reports will be made available for your review
- The above information and subsequent report can be shared with MDHHS leadership, Judges, and other stakeholders

---

From: Sanches, Christine (DHHS) <SanchesC@michigan.gov>
Sent: Thursday, November 5, 2020 9:16 AM
To: Bladen, Stacie (DHHS) <BladenS@michigan.gov>
Cc: Smith, Terri (DHHS) <SmithT42@michigan.gov>; Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>; Brown, Carolyn (DHHS) <BrownC54@michigan.gov>
Subject: RE: Urgent: Significant Development with AverHealth Drug Testing Errors

Stacie,

Please keep us informed, and let us know if you need anything from BGP. I've copied Terri, Carolyn, and Sarah for awareness. Terri is forwarding your email to the DTMB Buyer Brandon Samuel.

Chris

From: Bladen, Stacie (DHHS) <BladenS@michigan.gov>
Sent: Wednesday, November 4, 2020 5:12 PM
To: Sanches, Christine (DHHS) <SanchesC@michigan.gov>
Subject: FW: Urgent: Significant Development with AverHealth Drug Testing Errors
Importance: High

Heads up. I'm just seeing this. We may be headed toward ending this contract. Not sure. Will doing further investigation.

From: Chang, Jooyeun (DHHS) <ChangJ4@michigan.gov>
Sent: Wednesday, November 4, 2020 4:31 PM
To: Ackert,Terence <terence.ackert@kentcountymi.gov>; Sue Dobrich <SueD@cassco.org>; Judge Dorene S. Allen <doreneallen@co.midland.mi.us>; Kelly Wagner <wagnerk@courts.mi.gov>; Cunningham, Jacob James <cunninghamjj@oakgov.com>; Nancy Thane <nthane@tuscolacounty.org>; Smart, Richard <Richard.Smart@3rdcc.org>; Jocelyn Fabry <jfabry@saulttribe.net>; Cheryl Hill <CHill@mqtco.org>; Langton, Lisa <langtonl@oakgov.com>; Mcnabb,Deborah <Deborah.mcnabb@kentcountymi.gov>; Feeney,Kathleen <kathleen.feeney@kentcountymi.gov>; Elizabeth Clement <ClementE@courts.mi.gov>; Megan Cavanagh <CavanaghM@courts.mi.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>; Rummel, Sandra (DHHS) <RummelS1@michigan.gov>; Bladen, Stacie (DHHS) <BladenS@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Wrayno, Jennifer (DHHS) <WraynoJ@michigan.gov>
Subject: RE: Urgent: Significant Development with AverHealth Drug Testing Errors
Importance: High

Judge Ackert – thank you for your email. We will look into this immediately and keep you and the other judges on this chain updated.

From: Ackert,Terence <terence.ackert@kentcountymi.gov>
Sent: Wednesday, November 4, 2020 4:20 PM
To: Sue Dobrich <SueD@cassco.org>; Judge Dorene S. Allen <doreneallen@co.midland.mi.us>; Kelly Wagner <wagnerk@courts.mi.gov>; Cunningham, Jacob James <cunninghamjj@oakgov.com>; Nancy Thane <nthane@tuscolacounty.org>; Smart, Richard

<Richard.Smart@3rdcc.org>; Jocelyn Fabry <jfabry@saulttribe.net>; Cheryl Hill <CHill@mqtco.org>; Langton, Lisa <langtonl@oakgov.com>; Mcnabb,Deborah <Deborah.mcnabb@kentcountymi.gov>; Feeney,Kathleen <kathleen.feeney@kentcountymi.gov>; Elizabeth Clement <ClementE@courts.mi.gov>; Megan Cavanagh <CavanaghM@courts.mi.gov>
Cc: Chang, Jooyeun (DHHS) <ChangJ4@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Rummel, Sandra (DHHS) <RummelS1@michigan.gov>
Subject: Urgent: Significant Development with AverHealth Drug Testing Errors

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Greetings:

I received a telephone call today from Dr. Sarah Riley, the former director of labs at AverHealth. If you will recall, Dr. Riley participated in the joint Zoom meeting with us and other representatives at AverHealth in October. Dr. Riley also participated in a call with AverHealth and members of the Parent and Children's Section of the Grand Rapids Bar Association in late October.

Dr. Riley informed me that last night she terminated her position as Lab Director with AverHealth because of her serious concerns that AverHealth has failed to follow standard testing procedures and is not compliant with the standards developed by the College of American Pathologists. AverHealth is accredited by the College of American Pathologists and emphasized that accreditation at our meeting in October. Dr. Riley advised me that she has filed a formal complaint against AverHealth with the College of American Pathologists.

The basis of her complaint, and the concern she raised with me, is that AverHealth does not follow the standard quality control procedures when conducting a test and reporting the results to the client. Dr. Riley stated that a test should be prepared, conducted, analyzed, and then re-tested under the required protocols to confirm the results before releasing the results. Individuals at AverHealth have shortened this process to only one test and analysis because they believe AverHealth has a good test record. Dr. Riley wanted to raise these concerns at our meeting but was directed not to do so.

Dr. Riley states that in certain circumstances the failed procedures can

create a false positive, especially with cocaine, in approximately 30% of the tests. The frequency of a false positive could, in some instances, increase to 50%.

I considered Dr. Riley's statements and her tone during our conversation to be credible. I was not left with the impression that she was a disgruntled employee or had some "axe to grind." Dr. Riley gave me authority to share this information.

However, without further investigation, I cannot verify her claims. Nevertheless, this information is significant and calls into question the entire DHHS testing protocol under AverHealth.

I am providing this information to each of you because you have been involved in our meetings with AverHealth. I believe this has to be investigated by DHHS, and the judges on this communication must be kept informed, and a plan for action and redress prepared.

Best Regards,

TJ

T. J. Ackert
Judge
Kent County Circuit Court
Family Division and Specialized Business Docket
180 Ottawa Avenue NW, Ste. 10200B
Grand Rapids, MI 49503
616-632-5091

<image001.png>

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PROHIBITED. If you have received this transmission in error, please immediately notify us by telephone. Thank you.

From: Doane, Amanda (DHHS)
To: Hannahs, Chad (DHHS)
Cc: Culp, Shaun (DHHS); Goad, Sarah (DHHS); Parks, Colin (DHHS)
Subject: RE: Memo regarding drug testing issue in child welfare cases
Date: Friday, November 13, 2020 6:38:00 AM

Chad,

This letter was the result of a disgruntled employee of Averhealth calling a judge and giving false information. That judge in turn sent out a letter to all judges passing along the false information. We are having a meeting with some judges this morning and hopefully can get this contained and corrected soon.

Amanda

From: Hannahs, Chad (DHHS) <HannahsC@michigan.gov>
Sent: Thursday, November 12, 2020 4:33 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Culp, Shaun (DHHS) <CulpS@michigan.gov>; Goad, Sarah (DHHS) <GoadS@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: FW: Memo regarding drug testing issue in child welfare cases

FYI, completely unrelated (as the case this morning was on a guardianship case), our County Prosecuting Attorney who represents us in our FC cases and CPS cases, just sent me this. I will reach out to our prosecutor and give them some preliminary information.

I look forward to the additional communication for the courts and the field.

From: Emily Hills <EHills@calhouncountymi.gov>
Sent: Thursday, November 12, 2020 4:27 PM
To: Hannahs, Chad (DHHS) <HannahsC@michigan.gov>
Subject: FW: Memo regarding drug testing issue in child welfare cases

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I was not sure if you have seen this but it is not making me happy.

From: Starling, Demetrius (DHHS)
To: Reinke, Jamie (DHHS); Walbecq, Deborah (DHHS)
Subject: More Averhealth follow up
Date: Friday, November 13, 2020 8:23:00 AM

The BSC Directors met with Colin and Stacie yesterday. More information will be coming very shortly and a letter from Averhealth will be sent to SCAO to disseminate to the Judges. In a quick nutshell:

1. We have determined that the complaint filed by the worker who resigned from Averhealth is not accurate.
2. The issues are around the level assigned to the testing which is being changed (not sure a solid date of when is yet available) not that testing is being done incorrectly or frauduently
3. We should continue to use Averhealth UNLESS the Judge orders us to utilize another agency.
4. As local vendors will vary greatly, we may want to begin searching and developing a process for referrals with our local offices.
5. The payment process would be how it was in the past, on a 93 through MiSACWIS. We will need to ensure that our office is set up as a provider in MiSACWIS. We should be getting something either through Colin or Amanda Doane on a fee scale.
6. If we or our courts have any issues with a test or Averhealth, I will need to know so that I can funnel that info to Colin and Amanda know immediately.

I hope this answers the current questions, but if not, please let me know. I know this has been incredibly hard on our staff who have reported for some time concerns with Averhealth.

From: Parks, Colin (DHHS)
To: Samuel, Brandon (DTMB)
Cc: Doane, Amanda (DHHS); Smith, Terri (DHHS); Parks, Colin (DHHS)
Subject: Averhealth
Date: Tuesday, November 17, 2020 6:58:40 AM

Hi Brandon,

Hope all is well. Some questions and concerns have been raised by our staff and the courts regarding the Averhealth/Aversys contract. The concerns of the court surround confidence in the testing process and, I believe to some extent, confidence in the company itself. Our goal is to maintain the contract, but to listen to the concerns of the court and consider amendments to the contract that may address/resolve those issues. Would you support me reaching out to some of those judges and see if we can have them provide suggestions to potentially amend the contract to address their concerns? Any other thoughts or suggestions?

Colin Parks
Manager, CPS Program Office
Michigan Department of Health and Human Services
235 South Grand Ave.
Lansing, MI, 48933
517.388.5125

From:	Doane, Amanda (DHHS)
To:	Ross, Robert (DHHS)
Cc:	Parks, Colin (DHHS); Scott Parrott - Field Operations
Subject:	Letter sent to judges with incorrect information
Date:	Wednesday, December 2, 2020 1:22:00 PM
Attachments:	AverhealthLetter.pdf image001.png

Bob,

I was forwarded the attached letter you sent out yesterday to your local family court judges. I wanted you to be aware of an incorrect statement in the letter:

In paragraph two, you indicate that …"MDHHS is not going to use Averhealth Drug testing services for 30-60 days" This statement is incorrect. MDHHS is still utilizing Averhealth during this time and if courts would like a county to utilize an alternative vendor for their cases, they may ask DHHS to do so. We are hoping that the misconceptions surrounding Averhealth are cleared up in the next 30-60 days. We are offering each court the opportunity to meet with Averhealth and their scientists to answer any questions the court may have to help resolve any issues.

Please let me know if you have any questions.

Amanda Doane
Department Analyst
Office of Child Welfare Policy & Procedure
Children's Services Agency
235 S. Grand Ave., Suite 510
Lansing, MI 48933
517-282-5273 work
517-241-7047 fax
DoaneA@michigan.gov

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From: Parks, Colin (DHHS)
To: Doane, Amanda (DHHS)
Subject: RE: BSC 3: Forensic Fluids *Immediate response
Date: Thursday, December 3, 2020 1:10:32 PM

Nice work, superstar!

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Thursday, December 3, 2020 1:43 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: BSC 3: Forensic Fluids *Immediate response

I had a group video call today with the judge from Calhoun County along with prosecutors, family attorneys, DHHS staff and Averhealth. All questions were asked and answered and I believe the judge will stay with Averhealth.

Amanda

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Thursday, December 3, 2020 12:21 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: FW: BSC 3: Forensic Fluids *Immediate response
Importance: High

FYI

From: Keathley, Faith (DHHS) <KeathleyF@michigan.gov>
Sent: Thursday, December 3, 2020 12:18 PM
To: Bladen, Stacie (DHHS) <BladenS@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Miller, Kathy Ann (DHHS) <MillerK11@michigan.gov>; Lowe, Laurie (DHHS) <LoweL@michigan.gov>
Subject: BSC 3: Forensic Fluids *Immediate response
Importance: High

Good afternoon,

No BSC 3 counties report currently using Forensic Fluids.

Please note the following additional comments:
Calhoun County reported that although it hasn't happened yet, they expect the Judge may order use of Forensic Fluids in the next week or two based on concerns with AverHealth's reports.
Muskegon County indicated their Court is not thrilled with AverHealth and anticipate the Court wanting Muskegon DHHS to explore other options.
Oceana County anticipates their Court may order the use of Forensic Fluids at some point due to the Prosecutor's objection to the current provider.

Please let me know if anything further is needed.

Thank you,

Faith Keathley
Administrative Assistant
Business Service Center 3
401 Eighth Street/PO Box 1407
Benton Harbor, MI 49023
Office Phone: 269-934-2178
Cell Phone: 616-202-8342
Facsimile: 269-934-2320
Email: keathleyf@michigan.gov

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From: Wrayno, Jennifer (DHHS) <WraynoJ@michigan.gov>
Sent: Thursday, December 3, 2020 8:35 AM
To: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Avery, Deborah (DHHS) <AveryD2@michigan.gov>; Borja, Kimberly (DHHS) <BorjaK@michigan.gov>; Milks, Michael (DHHS) <MilksM@michigan.gov>; Ray, Annie (DHHS) <RayA@michigan.gov>; Scheuer, Thomas M. (DHHS) <ScheuerT@michigan.gov>; Selden-Johnson, Savator (DHHS) <Selden-JohnsonS@michigan.gov>; Williams, Chontelle (DHHS) <WilliamsC18@michigan.gov>; Wright, Lynette (DHHS) <WrightL5@michigan.gov>; Baker, Adam (DHHS) <BakerA2@michigan.gov>; Johnson, Taseanda (DHHS) <JohnsonT39@michigan.gov>; LeFear, Kimberlee (DHHS) <LeFearK@michigan.gov>; Love, Verdetta C. (DHHS) <LoveV@michigan.gov>; Maplanka, Ivana (DHHS) <MaplankaI@michigan.gov>; Marcath, Karen (DHHS) <MarcathK@michigan.gov>; Orr, Scott (DHHS) <OrrS1@michigan.gov>
Cc: Marner, Shelly J. (DHHS) <MarnerS@michigan.gov>; Miller, Kathy Ann (DHHS) <MillerK11@michigan.gov>; Lovell, Luther (DHHS) <LovellL3@michigan.gov>; Campau, Wendy (DHHS) <CampauW@michigan.gov>; Bladen, Stacie (DHHS) <BladenS@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Williams, Douglas (DHHS) <WilliamsD11@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>
Subject: Immediate response needed: Forensic Fluids
Importance: High

Hi Urban Directors,
In my AM meeting with CSA a concern was brought forth about the levels that Forensic Fluids utilizes for their drug screens.

Please advise ASAP whether your county is using Forensic Fluids. Please send an email to me with a cc to Deb Avery.
Question 1 – does your county used Forensic Fluids? If no, no need to answer the other questions.
Question 2 - If yes, is it court ordered to specifically use them?
Question 3 - If not court ordered to specifically use them – do you have other options?

BSC Directors – can you please poll your team also and let Stacie/Colin know who is using them?

Thanks

Jennifer Wrayno, Regional Director
Business Service Center (BSC) 5
Children's Services Agency
3040 W. Grand Blvd, Ste 5-150
Detroit, MI 48201

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From: Doane, Amanda (DHHS)
Sent: Tue, 15 Dec 2020 21:16:19 +0000
To: Paul Jancha
Cc: rmcbryde@berriencounty.org; Alexis Morris; rfuller@triton.net; Colin Banyon; Robert Lutz; jprewozniak@bethany.org; cmuller@bethany.org; jherzog@averhealth.com; ddelagnes@averhealth.com; Parks, Colin (DHHS); Doane, Amanda (DHHS)
Subject: RE: Berrien County Courts & MDHHS Discussion with Averhealth

Mr. Jancha,

The meeting date and time was run through the court for their availability. If the court would like to reschedule the meeting or if you would like another meeting opportunity we can work to make that happen.

I am not sure what you are asking regarding "the involvement of the two testing agencies…". I am not familiar with the case and can only say that if you would like Averhealth to testify at a hearing please ask the caseworker to request this and Averhealth will be sure to testify to all results that have been confirmed through their lab.

The meeting on Thursday is a discussion with the court, prosecuting attorneys, family attorneys, MDHHS, Private PAFC Partners, Myself (the contract administrator) and Averhealth. There will be discussion regarding the Judge Boyd letter posted to SCAO and give Averhealth the opportunity to discuss the false allegations made by a past employee, along with their company information, accreditation and other information. There will also be plenty of time for the court, attorneys, and staff to ask questions directly of Averhealth on this or any other topic. I will also try to remember to record the Teams session and send the link out to all invitees after the end of the meeting

If you would like any other information or to meet with Averhealth separately please let me know and I will be happy to set something up for you.

Amanda Doane
Department Analyst
Office of Child Welfare Policy & Procedure
Children's Services Agency
235 S. Grand Ave., Suite 510
Lansing, MI 48933
517-282-5273 work
517-241-7047 fax
DoaneA@michigan.gov

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disclosure, or distribution of any confidential and/or privileged information contained in this e-mail is expressly prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

From: Paul Jancha <pauljancha@hotmail.com>
Sent: Tuesday, December 15, 2020 3:33 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: rmcbryde@berriencounty.org; Alexis Morris <amorris@bethany.org>; rfuller@triton.net; Colin Banyon <cbanyon@hotmail.com>; Robert Lutz <rblutz1@ameritech.net>; jprewozniak@bethany.org; cmuller@bethany.org
Subject: Re: Berrien County Courts & MDHHS Discussion with Averhealth

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Why was I not a part of setting up meeting? I can't do 12/17/20 noon meeting. Also, have any arrangements been made to involve the 2 testing agencies at the meeting which my client would like them to be a part of as set forth in the email from my client which I sent to Alexis Morris on 12/11/20?

Paul Jancha

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Tuesday, December 15, 2020 10:52 AM
To: Rory McBryde <rmcbryde@berriencounty.org>; Paul Jancha <pauljancha@hotmail.com>; Alexis Morris <amorris@bethany.org>; rfuller@triton.net <rfuller@triton.net>; Colin C. Banyon (cbanyon@hotmail.com) <cbanyon@hotmail.com>; Robert Lutz <rblutz1@ameritech.net>; Jamie Prewozniak <jprewozniak@bethany.org>
Subject: FW: Berrien County Courts & MDHHS Discussion with Averhealth
When: Thursday, December 17, 2020 12:00 PM-1:00 PM.
Where: Microsoft Teams Meeting

-----Original Appointment-----
From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Tuesday, December 15, 2020 7:06 AM
To: Doane, Amanda (DHHS); Courtney Muller; ddelagnes@averhealth.com; jherzog@averhealth.com; Nemitz, Stacy (DHHS); Celmer, Kim (DHHS); Tia Gipson
Cc: Parks, Colin (DHHS)
Subject: Berrien County Courts & MDHHS Discussion with Averhealth
When: Thursday, December 17, 2020 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting
Importance: High

Courtney & Stacy,

Can you please forward this to the courts, attorneys, MDHHS Managers, Private Partner Managers. This Teams meeting is to discuss the perceived issues with Averhealth and give all parties the opportunity to ask questions directly to Averhealth.

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Or call in (audio only)

[redacted] States, Pontiac

MCL 15.243(1)(u)

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From: Courtney Muller <cmuller@bethany.org>
Sent: Monday, December 14, 2020 3:42 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: Forensic Fluids

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Good Afternoon!

After consulting with the parties on this case, it looks like 12/17 at noon would work the best. Is this a possibility?

Thank you!!!

Courtney Muller

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Wednesday, December 9, 2020 1:54 PM

To: Courtney Muller <cmuller@bethany.org>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: Forensic Fluids

I will be happy to set that up. If you can ask the court for date/times that work for them, I will coordinate with Averhealth and get a Teams meeting set up. I can set it up and you can forward to the courts and whoever else the courts would like to be there. Please be sure to include the county as well.

Amanda

From: Courtney Muller <cmuller@bethany.org>
Sent: Wednesday, December 9, 2020 1:52 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Forensic Fluids

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Good Afternoon!

I've consulted with my program manager and the case manager on this case, and we feel that we should start with having the meeting with Averhealth and the court parties. How would I go about getting that set up? Should I go through you for that?

Thank you!!!

Courtney Muller

From: Courtney Muller
Sent: Wednesday, December 9, 2020 11:13 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Forensic Fluids

Thank you so much for meeting with me today and for all the information! I just sent a very detailed email to our prosecutor! I'll let you know of any follow up!!

Courtney Muller

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Wednesday, December 9, 2020 10:22 AM
To: Courtney Muller <cmuller@bethany.org>
Subject: RE: Forensic Fluids

From: Courtney Muller <cmuller@bethany.org>
Sent: Wednesday, December 9, 2020 9:26 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Forensic Fluids

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Hello! I'm only available at 10am today. Does that work?

Thank you!!

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Wednesday, December 9, 2020 9:04 AM
To: Courtney Muller <cmuller@bethany.org>
Subject: RE: Forensic Fluids

Are you available some time today to discuss? I can set up a Teams meeting.

Amanda

From: Courtney Muller <cmuller@bethany.org>
Sent: Wednesday, December 9, 2020 8:11 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: FW: Forensic Fluids

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Good Morning!!

Are you able to help me get started with Forensic Fluids?

Thank you!!!

Courtney Muller

From: Nemitz, Stacy (DHHS) <NemitzS@michigan.gov>
Sent: Wednesday, December 9, 2020 7:10 AM
To: Courtney Muller <cmuller@bethany.org>
Cc: Celmer, Kim (DHHS) <CelmerK@michigan.gov>; Tia Gipson <GipsonT@michigan.gov>
Subject: RE: Forensic Fluids

Good Morning Courtney,

So far Berrien DHHS has not had to deal with using an outside vendor (yet)! If I were you I would reach out to Amanda Doane (doanea@michigan.gov). She handles the contract and should be able to assist with how to pay FF.

Also, I just received the clarification below regarding PAFC's – just want to make sure you are aware you will have to send your own spreadsheet to Amanda.

The local PAFC agencies should work with the county but ultimately will have to submit a spreadsheet to me for each county they work in, They will have to work with the alternate provider to get supplies (these MUST be kept separate from the Averhealth supplies), and the invoices for supplies, shipping, testimony, etc. are to be sent to the Federal Compliance mailbox for payment.

Thank you!!

Stacy Nemitz
Departmental Analyst
Berrien County Department of Health & Human Services
401 Eighth St., PO Box 1407
Benton Harbor, MI 49022
Fax: (269) 934-2115
Email: Nemitzs@michigan.gov

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From: Courtney Muller <cmuller@bethany.org>
Sent: Wednesday, December 9, 2020 5:35 AM
To: Nemitz, Stacy (DHHS) <NemitzS@michigan.gov>
Cc: Celmer, Kim (DHHS) <CelmerK@michigan.gov>; Gipson, Tia (DHHS) <GipsonT@michigan.gov>
Subject: Forensic Fluids

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Good Morning!

We are looking to refer a client to Forensic Fluids for screening. I called Forensic Fluids last week to start that process. I was able to speak with their sales rep yesterday. She reported that they've been hearing from a lot of agencies (since the new CI came out). However, she reported that no one had figured out how to pay for the service yet.

She reported that they can reopen our Bethany account and mail screens to us. It was reported that we can't use any of their testing sites because they are not the contract with DHHS.

She reported that they need to be paid up front; which she clarified to mean, that they can mail us the screens, but then they'll need to be paid within 30 days of that.

She reported that it sounded like some agencies might just pay them and then have DHHS reimburse them, and others might be getting the DHS-93 approved prior and having DHHS pay directly.

I'm wanting to try to get approval first. So I'm wondering how I can do that. If I put in a forensic fluid case service, can I put in the number of screens (units) we want approved and how much each are ($35)? Does that make the most sense? Or does another way make more sense?

Let me know what your thoughts are. Thank you!!!

Courtney Muller, LLMSW
Foster Care Supervisor
Bethany Christian Services
C: (269) 615-1700 | T: (269) 372-8800 | **Bethany.org**
6687 Seeco Drive, Kalamazoo, Michigan 49009-5970 (map)

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Redaction Log

Total Number of Redactions in Document: 1

Redaction Reasons by Page

Page	Reason	Description	Occurrences
3	MCL 15.243(1)(u)	(23) Records of a public body's security measures, including security plans, security codes and combinations, passwords, passes, keys, and security procedures, to the extent that the records relate to the ongoing security of the public body.	1

Redaction Log

Redaction Reasons by Exemption

Reason	Description	Pages (Count)
MCL 15.243(1)(u)	(23) Records of a public body's security measures, including security plans, security codes and combinations, passwords, passes, keys, and security procedures, to the extent that the records relate to the ongoing security of the public body.	3(1)

Subject: Two quick questions
Location: Microsoft Teams Meeting

Start: Tue 12/01/2020 10:00 AM
End: Tue 12/01/2020 10:30 AM
Show Time As: Tentative

Organizer: Doane, Amanda (DHHS)
Required Attendees: Jason Herzog;Parks, Colin (DHHS)
Optional Attendees: Dominique Delagnes;Jacquie Sheehey

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Or call in (audio only)
MCL 15.243(1)(u) United States, Pontiac
Phone Conference ID: MCL 15.243(1)(u)
Find a local number | Reset PIN

Learn More | Meeting options

From: Jason Herzog <jherzog@averhealth.com>
Sent: Monday, November 30, 2020 7:15 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Dominique Delagnes <ddelagnes@averhealth.com>; Jacquie Sheehey <jsheehey@averhealth.com>
Subject: Re: Two quick questions

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Good morning Colin and Amanda,

Can we schedule thirty minutes on Tuesday to discuss cutoff levels, December training, SCAO, CAP, and other related topics? We are open except for 10-11 and 1-2:30.

We have been advised not to release Sarah Riley's contact information. Not because we are against Joo speaking with Ms. Riley, but because Ms. Riley sent a demand letter for $1.25 million and because of a potential confidentiality violation. Though, we welcome a conversation between Joo and Dr. Michele Glinn. Would you like contact information for Dr. Glinn?

Per your request, attached is the correspondence we received from CAP regarding Ms. Riley's false allegations. One of the allegations regards the review of quality control results, which was one of Ms. Riley's job duties that she failed to complete. Dr. Glinn has since brought all reviews current and fortunately there were no issues in the results.

Many thanks,
Jason

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

> On Nov 24, 2020, at 3:22 PM, Parks, Colin (DHHS) <ParksC@michigan.gov> wrote:
>
> Joo has indicated she would like to contact her.
>
> I am not surprised to hear that about Forensic Fluids. I will contact our Contract folks and ask them for suggestions. We do know they are sending letters to county directors and front line staff indicating same.
>
> ---
>
> From: Jason Herzog <jherzog@averhealth.com>
> Sent: Tuesday, November 24, 2020 3:19 PM
> To: Parks, Colin (DHHS) <ParksC@michigan.gov>
> Cc: Dominique Delagnes <ddelagnes@averhealth.com>
> Subject: Re: Two quick questions
>
> **CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov**
>
> I am not sure if we are allowed to share Sarah's contact information. Who plans to contact her?
>
> We have also learned that Forensic Fluids is going court to court with the MDHHS memo informing each county that they can switch providers.
>
> Jason Herzog
> ceo

o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

On Nov 24, 2020, at 2:00 PM, Parks, Colin (DHHS) <ParksC@michigan.gov> wrote:

EXTERNAL: This email originated from outside averhealth. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

I was asked to see if you can send/resend the complaint letter filed by Dr. Riley and a way to contact her. Are both of those possible?

Colin Parks
Manager, CPS Program Office
Michigan Department of Health and Human Services
235 South Grand Ave.
Lansing, MI, 48933
517.388.5125

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Redaction Log

Total Number of Redactions in Document: 2

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Redaction Log

Redaction Reasons by Exemption

Reason	Description	Pages (Count)
MCL 15.243(1)(u)	(23) Records of a public body's security measures, including security plans, security codes and combinations, passwords, passes, keys, and security procedures, to the extent that the records relate to the ongoing security of the public body.	1(2)

averhealth

TO: Colin Parks, Manager CPS Program Office and Amanda Doane, Department Analyst Office of Child Welfare Policy & Procedures

FROM: Jason Herzog, CEO Averhealth

DATE: December 1, 2020

SUBJECT: Request to Conclude MDHHS Investigation & Ask SCAO to Issue a New Memo

---

The allegations raised by Sarah Riley ("Riley") harm the Averhealth brand and the trust that so many members of the Averhealth family have worked tirelessly to earn over the past 25 years. Because of these allegations, SCAO published a statewide memo and MDHHS initiated an investigation. Averhealth takes these events very seriously and has and will continue to work to eliminate any form of doubt and fully restore the good name of Averhealth. Concluding the MDHHS investigation and issuing a new SCAO memo will greatly advance the elimination of doubt and restoration of the Averhealth name.

Based on the following fact pattern, we ask that MDHHS conclude its investigation and that MDHHS ask SCAO to issue a revised memo.

On Thursday, October 29, the Averhealth leadership team met for a full day of planning. This team is comprised of nine people and included Riley. Riley did not raise a single concern during this meeting, despite multiple opportunities to do so. On Friday, October 30, the day following the meeting Jason Herzog ("Herzog") and Riley exchanged an email (see Attachment A) where Riley shared how much she enjoyed getting to know the team and was looking forward to working with everyone. Four days following this email exchange, Riley abruptly resigned without notice and has yet to discuss a single concern with any member of the Averhealth team.

On Thursday, November 5, Averhealth learned that Riley raised allegations regarding "…Averhealth employee practices not complying with the company's accreditation standards…[specifically]…a test should be prepared, conducted, analyzed, and then re-tested under the required protocols to confirm the results before releasing the results". As described in the following bullets, through unanimous agreement that direct to chromatography is forensically acceptable, this statement has been conclusively refuted by multiple independent experts and documentation published by the United States Department of Health and Human Services Centers for Medicare and Medicaid ("CMS").

- On 11/6/2020, Averhealth provide MDHHS with the CMS Local Coverage Determination ("LCD"), which states, "it is necessary to go direct to chromatography to i) identify a specific substance or metabolite that is inadequately detected…or not detected by immunoassay". Due to the very low cutoff levels used by MDHHS an immunoassay method cannot adequately detect or simply cannot detect specific substances.

- On 11/13/2020, the Michigan Department of Health and Human Services Chemistry and Toxicology Division and Infectious Disease Division confirmed that, "…the use of chromatography testing (and no immunoassay) was appropriate."
- On 11/14/2020, Paul Cary, an independent expert and member of the NADCP faculty, in response to questions asked by Judge Dobrich stated, "Some laboratories…utilize LC/MS/MS technology…for BOTH screening and confirmation – thus eliminating the immunoassay initial screening. This is considered a forensically acceptable approach. Mass-spectrometry is a high-resolution technology that is highly accurate and reliable."
- On 11/16/2020, the Michigan Bureau of Labs stated "…it is possible…to use chromatography alone".

During the week of November 16, Averhealth conducted an internal investigation and prepared a response the complaint that Riley filed with the College of American Pathology ("CAP"). The CAP complaint sited concerns regarding: i) mass spectrometry confirmation testing; ii) failure to follow procedures as written; iii) concerns regarding instrument calibration; and iv) concerns regarding reviews of quality control results. The mass spectrometry confirmation testing has since been conclusively refuted. The internal Averhealth investigation showed no issues with following procedures or instrument calibration, but there was no evidence that Riley completed the reviews of the quality control results. Completing reviews of quality control results was one of Riley's job duties. Dr. Glinn has since completed the reviews of quality control results and fortunately there were no issues. Further all of the concerns raised by Riley have been inspected by CAP on April 13, 2016, March 15, 2018 and February 7, 2020. These inspections always concluded with glowing remarks from the on-site inspectors. In addition, CLIA and the State of New York conducted on-site surveys in late 2019, also resulting in positive remarks from the on-site inspectors. Averhealth has a proven track record with CAP and other certifying organizations.

On the Thursday, November 19, Riley demanded that Averhealth pay her $1,250,000 within 15 days in exchange for a full release of all complaints. Riley claims that she was a whistleblower and we forced her to resign. Obvious faults with this complaint, beyond false allegations, include: i) just four days before Riley resigned, she shared how much she looked forward to working with everyone at Averhealth; ii) Riley never once raised any concerns internally; iii) Riley resigned before raising any concerns; and iv) Riley was directly responsible for every concern that she raised.

The below table provides a summary of key milestones.

Date	Day	Time	Activity [1]
10/29	Thursday	Full Day	Averhealth Leadership Team Meeting (Riley participated in this meeting)
10/30	Friday	10am	Herzog emails Riley sharing how nice it was to meet and that he was looking forward to learning from and with Riley.
10/30	Friday	4pm	Riley responds to Herzog's emails sharing that she enjoyed meeting the team and was looking forward to working with everyone.
11/1	Sunday	12pm	Riley emailed Dominique Delagnes ("Delagnes") regarding four continuous improvement ideas and her plan to implement.
11/1	Sunday	3pm	Delagnes approved Riley's plan and asked that she balance turnaround time with the proposed improvements (i.e., do not forsake one for the other).

11/3	Tuesday	10am	Delagnes and Riley conducted a standing call. Riley gave an update on the planned improvements. Delagnes offered to help, which Riley said was not necessary because she could manage.
11/3	Tuesday	After hours	Riley asked a male co-worker to help her carry some personal items to her car. Riley told the male co-worker that she was "moving things around". Averhealth later learned that Riley had cleaned out her office.
11/4	Wednesday	Unknown	Riley called Judge T.J. Ackert to voice concerns.
11/5	Thursday	7am	Averhealth learned of the call between Riley and Judge T.J. Ackert via an email from MDHHS.
11/5	Thursday	Multiple	Delagnes left voicemails and sent text messages to Riley. Riley has not responded to any contact attempts.
11/5	Thursday	8am	Riley submitted a letter of resignation via email to Delagnes, effective Tuesday 11/3/2020.
11/6	Friday	N/A	Averhealth provided the United States Health and Human Services Centers for Medicare and Medicaid Local Coverage Determination that refutes the specific concern Riley shared with Judge Ackert.
11/11	Wednesday	N/A	Averhealth was notified that Riley filed a complaint with CAP.
11/13	Friday	N/A	Michigan Department of Health and Human Services Chemistry and Toxicology Division and Infectious Disease Division refuted the specific concern Riley shared with Judge Ackert.
11/14	Saturday	N/A	Paul Cary, a member of the NADCP faculty, refuted the specific concern Riley shared with Judge Ackert.
11/16	Monday	N/A	Michigan Bureau of Labs refuted the specific concern Riley Shared with Judge Ackert.
Week of 11/16		N/A	Averhealth conducted an internal review and prepared a response to the CAP complaint finding only that weekly quality control reviews, a Riley job duty, were not completed. Dr. Glinn completed the past due quality control reviews and fortunately there were no issues.
11/19	Thursday	N/A	Riley demanded that Averhealth pay her $1,250,000 within 15 days in exchange for a full release of all complaints.

[1] Copies of supporting documents are available upon request.

Attachment A

From: **Sarah Riley** SRiley@averhealth.com
Subject: Re: Welcome to Averhealth
Date: October 30, 2020 at 4:38 PM
To: Jason Herzog jherzog@averhealth.com

SR

Thank you for including me! I am enjoying CYL and learning a lot. I've also really enjoyed getting to know the team. I'm looking forward to working with everyone.

Have a good weekend,
Sarah

Get Outlook for iOS

From: Jason Herzog <jherzog@averhealth.com>
Sent: Friday, October 30, 2020 10:25:00 AM
To: Sarah Riley <SRiley@averhealth.com>
Subject: Welcome to Averhealth

Sarah,

It was a pleasure meeting you yesterday. Very much looking forward to learning from you and learning with you.

Thanks for joining the Averhealth team.

Hope that you have a spooky safe Halloween with your littles.

Many thanks,
Jason

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

Transition Planning

CPS Program Manager Projects/Responsibilities

Annual Progress and Services Review (APSR)/State Plan – CPS Program Office receives requests for APSR updates in the late winter/early spring. The data analyst acts as lead for updates (including requests for updates from other offices) on policy, practice, and system changes. These updates have a tight timeframe. Kevin has acted as lead and does a great job with them.

Before finalization, these require multiple reviews prior to submission to CSA leadership. APSR updates also require the annual Citizen Review Panel reports. NOTE: CRP reports are written by the CRP's- to the department. Any changes should be done in consultation with the CRP's and with their support. Upon finalization, these are sent by DCQI to the Children's Bureau (CB).

Nancy Rygwelski with DCQI provides us these documents for updates and they are submitted to her (after CSA review) for submission.

Staff Collaboration As mentioned above, Kevin is the primary for all APSR. He coordinates that work with others. Also, as mentioned, Nancy Rygwelski (and, by extension, Kelly Sesti) report the information back to the CB.

Averhealth- This is the company currently responsible for the MDHHS substance use screening contract. The department modified previous approach of utilizing local labs/providers to a statewide contract to ensure consistency in testing and reduce taxpayer cost.

Amanda Doane is the contract administrator and in that role is highly aware of process, concerns and needs. Would suggest Amanda is aware of any/all discussions having to do with this contract- her historical knowledge and attention to detail is invaluable.

Multiple issues were raised to department attention from field and courts regarding this contract (either I or Amanda can provide all relevant communications/developed messaging to ensure you are up to date). The past concerns of courts were raised by a few judges and over the past 3-4 months have been addressed (two-panel testing, reliability/confidence in lab process) through the assessment completed by Doctors Wagner and Broussard.

Those concerns resulted in guidance to the field/court, allowing for testing to be completed by alternative labs, until the report by Wagner/Broussard was complete. Those doctors will soon be providing recommendations for modification to level testing (this may also include suggestions for modifying testing procedures). The intent was always to return to Averhealth as the sole tester for the state (for the same reasons listed above).

There will be a need for the manager to stay in regular contact with Averhealth (contact below). Concerns with the court raised the latest round of issues, but this contract has a lot of moving parts and a lot of folks who will reach out to you with questions/concerns (field, court, legislators- we have had many express concerns re; use of local third-party administrators, and others).

Also, as the department moves forward with redesign, substance use testing will be something that will lead to ongoing changes in what we are testing for, how we test and many other factors. This will be the case regardless of the vendor and have been a hallmark of this contract.

Staff Collaboration Amanda Doane is primary. Kevin can also assist, as needed. You will want to stay in regular contact with Averhealth (Jason Herzog is the CEO) and Dominique Delanges. I would suggest at least a couple times a month if things are smooth.

Boilerplate- As of 2021, CPS Program Office had three boilerplate items which require reporting to the Michigan legislature:

Section 514- This is an annual report is due by the end of February. This report has been provided for well over a decade and includes statistical information on the CPS process (investigation, assignments, reporting elements), an overview of key items which have impacted the department in the previous year, as well a summary of all policy created in the past year.

Section 592- This section is part of Public Act 166 of 2019 and is a new report. The reporting elements for this are tied to the CPS audit findings (seven specific items) as well as audit observations regarding worker safety. This requires CPS office to conduct and assessment on workers sense of safety (via quarterly survey) and providing that information to the state legislature. We also provided these findings to CSA leadership and BSC and county directors for awareness and action.

Section 593- This requires an assessment and report to the legislators on the status of and supports (training and others) for model child abuse protocols (see CPL Section 8 (6)). CPS Office is working with PAAM training to assist with this training for staff, law enforcement and prosecutors.

Staff collaboration Kevin is the lead here as well He works with DMU to pull the data as needed and will review with you the messaging sent to the field. He also will be working with PAAM to ensure the PAAM contract includes training elements (GTF has also offered training for this as well. Suggest contacting Joe Merritt who oversees the GTF training committee to discuss. PAAM is a good partner in this piece (as the protocols require collaboration with prosecutors), however, other folks could train this. That will be a decision you may want to consider.

Casey Family Programs Recommendations (CFP)- CFP provided recommendations for policy changes in 2020. The recommendations were broken into three categories and three committees met to discuss the recommendations and provide suggestions for moving forward, or not, with the recommendations. The groups concluded meetings and discussions near the end of January/beginning February 2021. The next step was to roll the committees recommendations up and provide them to CSA for next steps. Marissa and Rachael can assist with moving this item forward.

Staff Collaboration Marissa and Rachael have taken the lead in this work. Marissa will be the person best able to roll up the recommendations from the three committees.

Central Registry – Changes to the central registry (CR) have been considered by CSA for over ten years. Numerous committees have been created to support changes which would modify the basis for placement on CR. Following hearing from the CPS audit (fall 2018), CSA leadership began discussions with Representative LeGrand (House Oversight Committee) to evaluate how to make these changes. Rep. LeGrand is seeking a broad and bipartisan coalition to support this change (so far, Licensing, LARA, tribes. Yet to be included, courts, schools, parents, faith-based communities).

Current proposed legislative changes would: Limit placement on CR to “serious acts” (section 17 & 18 of CPL) and delink placement on CR from use of the SDM tool. The group must evaluate how to ensure (in

the absence of CR) that current/potential licensed providers can be more thoroughly assessed before licensure.

Work already done includes: Multiple meetings with LARA, tribes, legislators, department leadership (including providing background to CSA and county leadership); multiple drafts of CR; proposed changes to PA 116; identification of internal and external partner needs (please see grid).

Work not done: Thorough evaluation of costs of change; obtaining data for CR demographics to provide at the time of hearing; discussion with monitors; coordination/information sharing with other partners; ongoing consultation and bill drafting with LARA/DCQI. Legislators want as much public support as possible. GTPAC members are aware of these proposed changes and want to support them. Legislators are also interested in these folks providing support and testimony. Joy can assist in making this happen.

Staff Collaboration This is one for which I was primary and had little staff involvement in our office. Collaborators in this work include our Legislative Office- Chardae Burton and Emily Schwarzkopf, LARA- Jason Scheeneman and Steve Gobbo, our Legal Office- Mary Brennan, CSA leadership- Stacie and Shayne, and the legislators and their staff.

Central Registry Clean-up- As part of the audit response, MDHHS was provided with a million dollars to be used for "clean-up" of the MDHHS central registry. Kevin is primary. This has multiple pieces:

- *U of M contract* Kevin oversees this contract. He and I worked with Joe and his staff to establish training for their students to review CPS reports and determine expunction (based on PA 30 of 2014). Kevin provides those reports to U of M on a regular basis. There is a need for consistent oversight here, as problems sometimes arise, and it is tied back to CPS audit remediation efforts.
- *Field Coordination part 1* Kevin and I would remain in contact with the field to request pulling of CPS reports (which fit established criteria for U of M review). This process is well established and other than some occasional contact with county leadership, likely no issues will arise.
- *Field Coordination part 2* However, given the scale of case pulls from larger counties, we have been working with DTMB and local office staff in our larger counties to extract, scan and send their reports. Cases are being pulled from Royal Oak Storage, with the assistance of DTMB, and provided to U of M. Five staff have been identified (including Neila Sanders) to meet one day a week at a DTMB building in Lansing to 1. Pull the correct reports (with CR listing) from the file boxes 2. Provide reports to staff who will scan and send them, and 3. Return those reports to the file boxes.
  NOTE: We are not sharing this broadly, but DTMB will maintain these files after this process is complete. We will be storing all files at a DTMB site, not Royal Oak Storage, moving forward.

Staff Collaboration Kevin and Neila, as well as Samantha Beyland with DTMB. As mentioned above, much collaboration with counties has occurred, including support from Savator Selden Johnson and Edna Nunn.

Child and Families Services Review- Responsible for reporting out on Assessment and Services PIP, in addition to CPS projects (SDM tool revisions).

Overview CPS Manager was responsible for obtaining quarterly updates on all items in assessment and services grid. This required contact with identified staff to obtain updates and providing those to DCQI. CPS updates include modification to PIP specific to the SDM tool. Initial goal was development of a

revalidated safety and risk assessment tool, policy and system changes to those tools and training. CPS responses have changed, as those tools will now be revised, and those changes will occur after Q8. Changes made reflect that approach and have been shared with the Children's Bureau.

Next steps Suggest collaboration with Theresa Keyes. Q8 ends at the end of April. Ensuring Children's Bureau supports our approaches responses and that the final goals are met are imperative.

Staff collaboration Kevin B., Theresa K., all those offices listed for reporting still due for Q7/8, DCQI staff, DMU staff, contracts, and others.

Committees- Our office has traditionally played a role in various committees, either as members or chairs of the following:

CPS Advisory Committee Made up of about two dozen CPS supervisors statewide. Makeup of the group is specific to CPS supervisors only and rotates membership annually (2-3 years for each supervisor). Meetings are quarterly when in person (monthly, during COVID-19) and include an annual conference. Discussion includes policy and program updates, field input/best practices and support. Meetings are chaired by CPS manager and coordinated by a CPS analyst and funded via CPS budget (<$10,000 annual). Contact with members is consistent throughout the year as a sounding board for changes in child welfare, best practices, and peer-to-peer support.

Staff collaboration This has historically been the CPS policy writer as meeting coordinator and me as the chair. With the departure of the policy writer from the CPS office, this will need to be reconfigured. Kevin may be a help here.

Citizen Review Panels (CRP) As with all states, Michigan is federally required (through receipt of CAPTA dollars) to assist with the development and support of three CRP teams: Child Abuse/Neglect and Foster Care (overseen by GTFCAN); Child Death (overseen by the Child Death State Team), and Prevention (overseen by the Prevention Councils). CRP's are responsible for activities throughout the year, consistent with their charge (addressing gaps/needs and reporting back to MDHHS) and providing an annual summary of that work to the department. CPS Program Office has gathered these reports, provided them for internal CSA leadership review, and submitting them with our annual State Plan (and costs incurred would be paid through CAPTA dollars).

Staff collaboration Kevin is primary here. Contacts for the CRP team leads are: Prevention CRP- Suzanne Greenburg; Child Death CRP- Heid Hilliard; CPS and Foster Care CRP- Dr. Laws Barker (with the GTF).

Child Death State Team Group is required by statute. Chair is CPS Program Office manager. The team is coordinated by MPHI (via contract, along with their role coordinating local child death teams) and meets quarterly. CPS Program office provides annual training at the CDR State Team conference. Group meets quarterly, reports trends/practices/findings from local teams. Typically includes national updates. Group meets quarterly and develops and annual report for the department (typically provided in early spring). The work of the local teams and state teams (as well as training for safe sleep) is covered through the contract with MPHI and paid for through CAPTA dollars (approximately $300,000 annually).

> The Child Death Citizen Review Panel is made up of State Team members. This group reviews child death cases, makes recommendations. CRP team meets 2-4 times per year. Findings also culminate in one of the three CRP reports referenced above.

Staff collaboration the meetings, chair role and review of the report are the role of the CPS Program Manager only.

Guy Thompson Parent Advisory Council Made up of about a dozen parents who have firsthand experience with child welfare, including many parents who have temporarily lost custody of their children. The council meets quarterly and is provided departmental updates, receives training and support from CSA. Members receive CPS policy to review and are included in the FDR process. One of the primary goals of the group are to increase parent advocacy and voice in child welfare. This has resulted in GTPAC members participation in legislative hearings, CFSR planning/federal engagement and training. Kevin and Joy have helped develop guidelines for this group and it is suggested they continue to play a role in supporting the group (verify with Joy, but I believe we have $50,000 budgeted). GTPAC is very interested in providing legislative testimony and support (please see CR changes above).

Staff collaboration This is primarily Joy Thelen, although Kevin does assist here. The CPS Program Office Manager should attend these meetings and help to facilitate opportunities for GTPAC members to become involved in a variety of MDHHS activities (policy development/review, training, and legislation, among others).

Mandated Reporter Committee Made up of about a dozen folks (field/central office, training, prevention council, CI, doctors), this group meets quarterly (sometimes, during training updates- monthly). This committee has ensured MR training is updated regularly, tools are developed, and that training is recorded and supported; both through OSDT and the Prevention Councils. Gwyn has been instrumental in the coordination of this group. Funding from CPS line has been used in support of training tools (along with funding from MSU Chance at Childhood and the Children's Trust Fund (no funding. Costs limited to printing, which has been absorbed by miscellaneous CPS budget line).

Staff collaboration Gwyn as primary, along with CPS Program Manager. Kevin also assists. OWDT (Michelle Coplin) can assist with training as needed.

Medical Advisory Committee (MAC) Made up of about a dozen pediatricians and medical experts from across the state. We allocate about $20,000 of our CPS budget to support their work. They meet quarterly and we coordinate (Joy). Meetings discuss CPS policy and initiatives and training needs. Up until two years ago, we primarily used funding to support an annual MAC conference. Those conferences are often very well attended. However, those attending are typically child welfare staff. We decided to modify the MAC approach for that funding and training, and we developed a statewide training for staff on how to assess and address abuse/neglect, using medical advice and support. Face to face training began prior to the pandemic and a webinar has replaced this. Online participation is strong, and feedback has been very positive. We are also saving much of the money allocated ($20,000).

Staff collaboration Joy as primary, along with CPS Program Manager.

CPS Audit- In August 2018, the CPS Audit conducted by the Office of the Auditor General (OAG) was provided to the department and the Michigan State Legislature. The large number of findings resulted in numerous remediation efforts undertaken by CSA (increased staffing support, improved worker safety practices and improved supervisory oversight), including the creation of the Supervisory Control Protocol.

In early summer of 2021, we were advised that the OAG would return to assess the work completed so far. Jordan Carter has been the lead in much of the audit reporting to the OAG and will be the primary in the coming months. However, it would be worthwhile for the director and manager of this office to review the 2018 audit findings, consult with Jordan and Rachael Wineland and make every effort to prepare for the auditors return.

The audit's release in 2018 received much attention, numerous hearings, significant press, and the oversight of a variety of legislators and the Governor's Office.

Staff collaboration as mentioned above, Jordan will be the audit lead. However, all the planning/prep for hearings, policy changes and work product were the role of the CPS manager.

CPS Budget- Our annual budget is typically in the ballpark of 1 million (1,048,300 in FY 2020). This is CAPTA dollars and is required to meet those CAPTA requirements (Nancy Rygwelski can provide). Allison Beckman tracks these dollars and their expenditure.

Money is spent on: Special projects (as needed funding. Has been spent on mandated reporter brochures, updates to the CPL, safe sleep messaging, field supports)- $200,000 NOTE: in 2020, $175,000 was used on the Alia contract. The Special Projects line is typically only $25,000; Safety and Risk Assessment- $50,000; Child Abuse and Neglect Conference/training- $19,500; CPS Advisory Committee and Conference- $9,000; Child Death Review Contract (includes local CDR teams and annual training)- $540,000; Medical Advisory Committee Conference- $0 (has been as high as $20,000 for MAC conferences); Reducing Fatalities and Recurring Injuries- $230,000.

Staff collaboration CPS Manager has sole oversight of spending, although these dollars result in contract spending overseen by analysts.

CPS Redesign- The redesign of CPS has been an identified goal for the department and is an effort to reduce CPS complaint assignment and confirmation by the introduction of front-end prevention approaches; to meet the safety concerns of the child and needs of the family absent CPS involvement.

Central Registry changes See above.

Centralized Intake (CI) assessment tools CPS Program office assisted with development of the NCCD and Evident Change (amended) contract to allow for an assessment of CI functioning and the development of an intake tool. Cross collaboration will occur between these contractors, in collaboration with MDHHS staff support. Kevin Bryan has managed this contract as the coordinator.

Staff collaboration CI staff, Jordan Carter as primary.

Maltreatment type changes Changes to CPS policy, specifically the CPS maltreatment types, began in 2020. The intent was to improve CPS investigators understanding and application of the different CPS maltreatments, and to better align those policies with the Michigan Child Protection Law. Draft of these changes have been through a wide variety of changes and feedback from many partners (field, CPS advisory, tribes, ARTT) has been considered and in some cases, incorporated. These meetings continue. Although the maltreatment type changes were nearing a decision-point, recent discussion has included pushing dates back (policy, training, systems) to a possible summer/fall 2021 release date, allowing for more discussion with external partners. These changes will be reviewed and discussed with Ideas42 and Evident Change on the week of March 1st, 2021.

Staff collaboration Marissa, Rachael, and Jordan.

Structured Decision-Making Tool (SDM) The SDM is required for use by statute and is tied by policy/statute to placement on the central registry. This link was never intended by the developers of the tool (NCCD, now known as Evident Change). MDHHS had contracted with Evident Change to revalidate the SDM tool and this decision was tied to the CFSR Performance Improvement Plan. During the tools review, and following decisions made by the department, it was decided that the greater benefit to the department/clients was to move away from revalidation and move toward development of new SDM tools (risk assessment, risk reassessment and safety assessment).

Although this resulted in a modification of the CFSR PIP (see above), it aligned with the departments desire to modify the central registry (see above) and the overall plans for CPS redesign; 1) By delinking placement on the central registry, the result is greater equity for parents caregivers, and 2) By development of SDM tools that more accurately assess safety and risk, the department is better equipped to keep children safe and provide families with services necessary to mitigate risk and increase family stability, and 3) The department can utilize the work done by Evident Change to move toward and effective intake assessment tool which will allow for more equitable and better decision making at the point of complaint intake.

Staff collaboration Kevin is primary. He drafted this contract and has regular contact with Evident Change. Marissa is also involved and Jordan Carter has regular contact with these contractors as a result of the CI assessment work (above).

Expunction Office- Our office has played a historic role in assisting with expunctions. That role changed after the CPS audit in the Fall of 2018. The Redaction/Expunction Unit was created and most of the oversight of these two processes was transferred to BSC 1 and Bobbi Jo and her staff. However, our office assists Bobbi Jo on a regular basis, and we remain involved in a regular meeting with Bobbi Jo, our legal office, MAHS and the AG's office. This includes two meetings per month, which I will forward to you. Also, Bobbi Jo will likely reach out for guidance and support on a regular basis to you/CPS office.

Staff collaboration CPS Program Office Manager, Kevin and Marissa.

Governor's Task Force (GTF) on Child Abuse and Neglect- The GTF is a thirty-year-old committee, independent of, but its coordination and grant oversight are housed within MDHHS. GTF receives annual support of nearly half a million dollars of federal funding through the Children's Justice Act (CJA) grant. This grant has specific requirements for this spending and the grant is renewed every year by the GTF coordinator. Joy, Kevin and Neila has significant background with the GTF and can likely answer any question you may have. Here are some high-level details:

- GTF membership is ascribed by the Governor's Office and their Appointments Office (Oralya Garza). Currently, a few appointments are pending their approval.
- Membership is determined by Executive Order and includes those who by employment or experience are experts in child welfare.
- There are over twenty current members and the task force is chaired by Detective Annie Harrison.
- The task force has multiple subcommittees, including a bylaws, training, protocol, and summit planning committee. Committees are added as needed.

- The task force meets four times per year, including an annual summit.
- There will be an immediate need to identify who the GTF coordinator should be. That had most recently been my role, with assistance from Kevin, Joy and Neila. I was in the process of and would suggest that you consider:
    - Redoing the position description of coordinator to full time (Annie agrees this would better meet GTF needs).
    - Placing Neila Sanders in the role of coordinator, with other staff's assistance as needed.
    - Oversight of any coordinator will be essential, based on the priority level of the task force and the need to always have a good understanding of what is going on, what the task forces needs are and problem solving with them before escalation.

Staff collaboration CPS Program Office Manager, Joy (currently overseeing organization and meeting planning), Kevin (currently overseeing billing, grant writing), Neila (providing minutes and back up support).

Office of Children's Ombudsman (OCO)- CPS Program Office receives Finding's and Responses from the OCO (provided by the Office of Family Advocate- see below) on a regular basis, and an annual report with findings and recommendations to the department. These reports often recommend suggested changes to policy and practice. Given the recent bifurcation of policy from program, where these responses may land is unknown. Responses have time frames attached and a review of our responses is provided to CSA leadership, via latter letter, prior to returning to the OFA; who is responsible for submitting to the OCO.

Beyond the response to these reports, CPS Program Office has tried to coordinate with OCO as often as possible. This includes meeting with OCO staff and discussing policy, joint trainings and providing an open line of communication. These efforts are always done with the awareness and support of the OFA.

Staff collaboration CPS manager.

Office of Family Advocate (OFA)- Work with the OFA and CPS Program is a regular occurrence. We coordinate with them on consultation with the field and assist in reviews of policy and practice. OFA currently houses staff for the Case Review Team and assistance with the Supervisory Control Protocol and our office works with those staff to ensure policy clarification. OFA and CPS Program Office co-developed the Safety by Design training, which has been provided to county offices throughout the state and led to revisions in safety planning policy enhancements.

OFA provides an annual report, which often has policy recommendations provided to CPS Program Office as well. The continued role of this office in assisting with that report is unknown.

Staff collaboration CPS manager.

State Liaison Officer- I was the State Liaison Officer (SLO) for Michigan. In that role, you are responsible for updating Michigan data and staying connected to other SLO's throughout the country. This provides you a perspective of what other states are doing specific to CPS. The SLO also typically attends the annual Children's Justice Act Annual Meeting (which coincides with the annual CDSR meeting- above). The meeting is held in Washington annually and it allows for the same opportunities for enhancing understanding of and collaboration with other states and even chances to bring those ideas back to

Michigan. Let me know who should be getting those notices (it should be Mary Lou, or the new manager) and I will let the SLO folks know to send you those details.

Staff collaboration CPS Manager only.

From: Parks, Colin (DHHS)
To: Mahoney, Mary Lou (DHHS); Starling, Demetrius (DHHS)
Cc: McCree, Derrick (DHHS); Parks, Colin (DHHS)
Subject: Transition Document
Date: Friday, March 5, 2021 10:11:36 AM
Attachments: Transition Document.docx

As mentioned in yesterdays meeting, I would update this as additional items came to me. This updated version provides background on CPS work with the CPS audit, our work with the OCO and OFA.

I'll continue to add as needed.

Please let me know if you have any questions.

From: Jarrad Wagner
To: Parks, Colin (DHHS)
Cc: Doane, Amanda (DHHS)
Subject: Re: Averhealth assessment
Date: Tuesday, December 8, 2020 10:10:49 AM

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Colin,
In general, a laboratory should be doing exactly what their lab manual says they are doing. We will review the lab manual to make sure the practices listed there meet forensic industry standards, and then we will observe employees while we are onsite, to ensure the employees are following appropriate procedures. This is similar to an NLCP audit, and Larry and I perform those thorough audits regularly. It will be modified slightly since this laboratory is not a SAMHSA/NLCP accredited laboratory, and this is something that we have done before. I do not have a full write-up and everything we will be looking at, but it will be in the report. If you want me to write up a full-scope it is possible, but I replied to your specific questions below.

- Validate Averhealth's testing process
  - We will audit their testing process to make sure that they are performing appropriate testing. We will observe the sample receipt process and verify that they are properly receiving specimens and documenting them. Then we will verify the analytical and reporting processes and that they are appropriate.
- Provide audit testing results (evaluating both positive and negative screen results),
  - We will ask for a list of test results in the past year or so, then select about 10 samples per month (80% positive) to review. We will identify the files we want to view so that the lab can assemble any and all supporting data with the reports, and we will verify that the data support the report. All specimens audited should have screening results and since some are positive we should see confirmation data. We will need to see some positives for each class being reported.
- Ensure the testing process meets CAP standards, (e.g., do Averhealth and FF have to follow CAP standards, even if they are accredited by different entities? Are they accredited by different entities?)
  - CAP is a fairly weak standard. We will identify any accreditations held by the lab and determine if the standards are being met. This may require access to audit records in possession of the laboratory.
- Identify and concerns re; staffing/testing process,
  - We will identify any concerns we have in relation to laboratory practices, including staff competency
- Assess that cut-off levels "make sense" and/or identify if levels should be adjusted (this will be an additional cost of $5,000), How are appropriate levels determined? Based on accreditation, best practice standards, or other?
  - Your original standards were setup by a laboratory that over-estimates the value of an oral fluid result, and is not concerned enough with specificity and practical

impacts of higher sensitivity (i.e. false positives). I am active on several national committees that are evaluating oral fluid cutoffs, mainly related to DUID. I am also involved in pain management testing that uses oral fluid instead of urine. Oral fluid generally contains the parent drug and not the metabolite (opposite of urine), so I will evaluate whether the analytical targets make sense. Also, I will review the goals of your testing and window of detection to help you determine if oral fluid is the appropriate specimen for your application. I am able to suggest an oral fluid screening device that could be used by your personnel onsite, as there are currently three options: Abbott Sotoxa, Draeger DT5000, and DrugWipe. This screen could be followed by a urine test that will capture a wider time frame of potential substance ingestion. The answer is best practice, but there are no specific accreditation requirements or published standards, and I believe your application is fairly unique.

- Identify cost, and time frame.
  - I thought I identified the costs- max of $15k.
    - 2 Day Laboratory Site visit, 2 inspectors (Dr. Wagner and Dr. Larry Broussard), and Report of Findings
      - $2500 each service fee, approximately $1000 travel expenses per person
    - Assessment of Specimen Type, Target Analytes and Sensitivity (Dr. Wagner and Dr. Curt Harper)
      - Will be between $5-8k, hourly at $300/hr
  - Timeframe
    - Depending on when the contract is setup, we could be done in a month or so. Larry and I will require a week after the site visit to write the report. They will require time to prepare the data packs for our audit. So hopefully we would be onsite before February 1, then we would report back to you by February 15th.
    - I may bring Dr. Curt Harper in for his oral fluid expertise when I evaluate your analyte list and sensitivity. But the contract will be with my company and I would make the arrangements.
    - I think March 1st latest submission date, and could be much sooner

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Tuesday, December 8, 2020 at 8:10 AM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Subject: FW: Averhealth assessment

CAUTION: This email originated from outside of the organization. Do not click links

or open attachments unless you recognize the sender and know the content is safe

Morning Jarrod,

We are moving toward establishing a payment process and I have copied Amanda Doane, our contract administrator as a contact person.

We have broadened the inquiry a bit and wanted to provide you with the specific questions our leadership is hoping the assessment will answer. Can you please let me know if these would be answered in your assessment and/or if any clarification is needed?

- Validate Averhealth's testing process,
- Provide audit testing results (evaluating both positive and negative screen results),
- Ensure the testing process meets CAP standards, (e.g., do Averhealth and FF have to follow CAP standards, even if they are accredited by different entities? Are they accredited by different entities?)
- Identify and concerns re; staffing/testing process,
- Assess that cut-off levels "make sense" and/or identify if levels should be adjusted (this will be an additional cost of $5,000), How are appropriate levels determined? Based on accreditation, best practice standards, or other?
- Identify cost, and time frame.

Colin Parks
Manager, CPS Program Office
Michigan Department of Health and Human Services
235 South Grand Ave.
Lansing, MI, 48933
517.388.5125

STATE OF MICHIGAN PROCUREMENT
Michigan.gov/MiProcurement

SCHEDULE A – STATEMENT OF WORK CONTRACT ACTIVITIES

Request For Proposal No. [redacted]
Assessment of Averhealth procedures

This schedule identifies the anticipated requirements of any Contract resulting from this RFP. The term "Contractor" in this document refers to a bidder responding to this RFP, as well as the Contractor who is awarded the contract. The term "Bidder" is used to identify where specific responses to the RFP are required.

The Contractor must respond to each requirement or question and explain how it will fulfill each requirement. Attach any supplemental information and appropriately reference within your response.

[Read and delete: To view a list of questions that should be considered when drafting a Statement of Work, refer to the *Statement of Work Interview Questions*.

BACKGROUND
Independent assessment of the policies and procedures of Averhealth, the statewide drug screening contractor for CPA and Foster Care

SCOPE
The scope of this project is to validate Averhealth's testing process, provide audit testing results (evaluating both positive and negative screen results). Ensure testing processes meet CAP-FDT standards, identify any concerns related to staffing/testing processes, assess what cut-off levels make sense and/or identify if levels should be adjusted

1. Requirements

1.1. General Requirements

- Validate Averhealth's testing process
  - Audit their testing process to make sure that they are performing appropriate testing. Observe the sample receipt process and verify that they are properly receiving specimens and documenting them. Verify the analytical and reporting processes and that they are appropriate.
- Provide audit testing results (evaluating both positive and negative screen results),
  - Ask for a list of test results in the past year or so, then select about 10 samples per month (80% positive) to review. Will identify the files to view so that the lab can assemble any and all supporting data with the reports, and will verify that the data support the report. All specimens audited should have screening results.
- Ensure the testing process meets CAP standards.
  - We will identify any accreditations held by the lab and determine if the standards are being met. This may require access to audit records in possession of the laboratory.

- Identify and concerns re; staffing/testing process, identify any concerns in relation to laboratory practices, including staff competency
- Assess that cut-off levels "make sense" and/or identify if levels should be adjusted. How are appropriate levels determined? Based on accreditation, best practice standards, or other?
    - Oral fluid generally contains the parent drug and not the metabolite (opposite of urine), so will evaluate whether the analytical targets make sense. Will review the goals of MDHHS testing and window of detection to help you determine if oral fluid is the appropriate specimen for your application. Suggest an oral fluid screening device that could be used by your personnel onsite.
- Identify cost, and time frame.
    - Maximum of $15,000, to include:
        - 2 Day Laboratory Site visit, 2 inspectors (Dr. Wagner and Dr. Larry Broussard), and Report of Findings
        - $2500 each service fee, approximately $1000 travel expenses per person
        - Assessment of Specimen Type, Target Analytes and Sensitivity (Dr. Wagner and Dr. Curt Harper)
        - Will be between $5-8k, hourly at $300/hr.
    - Timeframe (approximate)
        - Onsite visit to the Averhealth lab in St. Louis, MO by February 1, 2021
        - Report submission no later than March 1, 2021

1.2. Transition

~~[**Read and delete**: Describe transition language necessary for Contract execution. Post-contract transition language is in the Standard Contract Terms. If the language is not sufficient, mark the section in the Standard Contract Terms "Reserved," and insert appropriate post-contract transition language here.]~~

1.3. Training (Reserved)

~~The Contractor must provide the following training: [Identify the training requirements, for example, onsite, offsite, or internet-based training]~~

~~(OR)~~

~~The Contractor must explain its training capabilities and any training that is included in its proposal.~~

~~The Contractor must provide documentation and training materials.~~

SCHEDULE A – STATEMENT OF WORK CONTRACT ACTIVITIES

2. Services Levels

2.1. Timeframes

All Contract Activities must be delivered within 90 days from receipt of order. The receipt of order date is pursuant to the **Notices** section of the Standard Contract Terms.

2.2. Delivery

Delivery will be expected within [xx] calendar days upon date of order. Delivery will be made at _____.

3. Acceptance

3.1. Acceptance, Inspection and Testing

[**Read and Delete:** Use either the acceptance process defined in the **Acceptance** section of the Standard Contract Terms or define a different process in this section. If specific agency approvals are needed, the agency must identify the responsible position and review process.]

The State will use the following criteria to determine acceptance of the Contract Activities: [add details]

3.2. Final Acceptance

[**Read and Delete:** Use this section if necessary. Ongoing projects usually do not require Final Acceptance language. Final Acceptance is when the project is completed and functions according to the requirements. Any intermediate acceptance of sub-deliverables does not complete the requirement of Final Acceptance.]

4. Staffing

4.1. Contractor Representative

The Contractor must appoint [insert number and types of positions (e.g. Service Manager, Product Representative)] individuals specifically assigned to State of Michigan accounts, who will respond to State inquiries regarding the Contract Activities, answer questions related to ordering and delivery, etc. (the "Contractor Representative"). Bidder must identify its **Contractor Representative**.

The Contractor must notify the Contract Administrator at least [insert number of days] calendar days before removing or assigning a new Contractor Representative.

4.2. Customer Service Toll-Free Number

The Contractor must specify its toll-free number for the State to make contact with the Contractor Representative. The Contractor Representative must be available for calls during the hours of 8:00 am to 5:00 pm EST.

4.3. Technical Support, Repairs and Maintenance

The Contractor must specify its toll-free number for the State to make contact with the Contractor for technical support, repairs and maintenance. The Contractor must be available for calls and service during the hours of 8:00 am to 5:00 pm EST.

When providing technical support, the Call Center must resolve the caller's issue within [xx] minutes. If the caller's issue cannot be resolved within [xx] hours, on-site service must be scheduled. The on-site service must be performed within [xx] hours of the time the issue was scheduled for service.

Work Hours The Contractor must provide Contract Activities during the State's normal working hours Monday – Friday, 7:00 am to 6:00 pm EST and possible night and weekend hours depending on the requirements of the project.

4.4. Key Personnel

[**Read and delete**: Key Personnel are not always required. If required under the resulting contract, insert appropriate language in this section.]

The Contractor must appoint [insert number and description of the Key Personnel] individuals who will be directly responsible for the day-to-day operations of the Contract ("Key Personnel"). Key Personnel must be specifically assigned to the State account, be knowledgeable on the contractual requirements, and respond to State inquiries within _____ hours.

[**Read and delete**: Insert other information as necessary.]

Contractor's Key Personnel must be on-site at [location] during the following times: _____.

The State has the right to recommend and approve in writing the initial assignment, as well as any proposed reassignment or replacement, of any Key Personnel. Before assigning an individual to any Key Personnel position, Contractor will notify the State of the proposed assignment, introduce the individual to the State's Project Manager, and provide the State with a resume and any other information about the individual reasonably requested by the State. The State reserves the right to interview the individual before granting written approval. In the event the State finds a proposed individual unacceptable, the State will provide a written explanation including reasonable detail outlining the reasons for the rejection. The State may require a 30-calendar day training period for replacement personnel.

Contractor will not remove any Key Personnel from their assigned roles on this Contract without the prior written consent of the State. The Contractor's removal of Key Personnel without the prior written consent of the State is an unauthorized removal ("Unauthorized Removal"). An Unauthorized Removal does not include replacing Key Personnel for reasons beyond the reasonable control of Contractor, including illness, disability, leave of absence, personal emergency circumstances, resignation, or for cause termination of the Key Personnel's employment. Any Unauthorized Removal may be considered by the State to be a material breach of this Contract, in respect of which the State may elect to terminate this Contract for cause under the **Termination for Cause** section of the Standard Contract Terms. It is further acknowledged that an Unauthorized Removal will interfere with the timely and proper completion of this Contract, to the loss and damage of the State, and that it would be impracticable and

extremely difficult to fix the actual damage sustained by the State as a result of any Unauthorized Removal. Therefore, Contractor and the State agree that in the case of any Unauthorized Removal in respect of which the State does not elect to exercise its rights under Termination for Cause, Contractor will issue to the State the corresponding credits set forth below (each, an "Unauthorized Removal Credit"):

[**Read and delete**: The dollar values must be modified for each project. The amounts in (i) and (ii) are used for example only.]

(i) For the Unauthorized Removal of any Key Personnel designated in the applicable Statement of Work, the credit amount will be $25,000.00 per individual if Contractor identifies a replacement approved by the State and assigns the replacement to shadow the Key Personnel who is leaving for a period of at least 30 calendar days before the Key Personnel's removal.

(ii) If Contractor fails to assign a replacement to shadow the removed Key Personnel for at least 30-calendar days, in addition to the $25,000.00 credit specified above, Contractor will credit the State $833.33 per calendar day for each day of the 30-calendar day shadow period that the replacement Key Personnel does not shadow the removed Key Personnel, up to $25,000.00 maximum per individual. The total Unauthorized Removal Credits that may be assessed per Unauthorized Removal and failure to provide 30-calendar days of shadowing will not exceed $50,000.00 per individual.

Contractor acknowledges and agrees that each of the Unauthorized Removal Credits assessed above: (i) is a reasonable estimate of and compensation for the anticipated or actual harm to the State that may arise from the Unauthorized Removal, which would be impossible or very difficult to accurately estimate; and (ii) may, at the State's option, be credited or set off against any fees or other charges payable to Contractor under this Contract.

The Contractor must identify the Key Personnel, indicate where they will be physically located, describe the functions they will perform, and provide current chronological résumés.

A. The Contractor must identify all Key Personnel that will be assigned to this contract and include the following: [Read and delete items as needed]

1. Name and title of staff that will be designated as Key Personnel.

2. Key Personnel years of experience in the current classification.

3. Identify which of the required key personnel positions they are fulfilling.

4. Key Personnel's roles and responsibilities, as they relate to this RFP, if the Contractor is successful in being awarded the Contract. Descriptions of roles should be functional and not just by title.

5. Identify if each Key Personnel is a direct, subcontract, or contract employee.
6. Identify if each Key Personnel staff member is employed full-time (FT), part-time (PT) or temporary (T), including consultants used for the purpose of providing information for the proposal.
7. List each Key Personnel staff member's length of employment or affiliation with the Contractor's organization.
8. Identify each Key Personnel's percentage of work time devoted to this Contract.
9. Identify where each Key Personnel staff member will be physically located (city and state) during the Contract performance.

B. The Contractor must provide **detailed, chronological resumes** of all proposed Key Personnel, including a description of their work experience relevant to their purposed role as it relates to the RFP.

Qualifications will be measured by education and experience with particular reference to experience on projects similar to that described in the RFP.

4.5. Organizational Chart

The Contractor must provide an overall organizational chart that details staff members, by name and title, and subcontractors.

4.6. Disclosure of Subcontractors

If the Contractor intends to utilize subcontractors, the Contractor must disclose the following:

- The legal business name; address; telephone number; a description of subcontractor's organization and the services it will provide; and information concerning subcontractor's ability to provide the Contract Activities.
- The relationship of the subcontractor to the Contractor.
- Whether the Contractor has a previous working experience with the subcontractor. If yes, provide the details of that previous relationship.
- A complete description of the Contract Activities that will be performed or provided by the subcontractor.

4.7. Security

The Contractor will be subject the following security procedures: [Read and delete: List the required procedures, for example, background checks (types, covered timeframe, and required documentation), clearly identifying uniforms, signing security forms, attending security training etc. Identify any agency specific security or confidentiality disclosure requirement identify.]

The Contractor must explain any additional security measures in place to ensure the security of State facilities. The State may require the Contractor's personnel to wear State issued identification badges.

The Contractor's staff may be required to make deliveries to or enter State facilities. The Contractor must: (a) explain how it intends to ensure the security of State facilities, (b) whether it uses uniforms and ID badges, etc., (c) identify the company that will perform background checks, and (d) the scope of the background checks.

4.8. Access to Tax Information

[**Read and delete:** Include this section as needed. If the Contractor will be receiving or handling tax information, both the *Exhibit 7 Safeguarding Contract Language of IRS Publication 1075* (www.irs.gov – click Forms & Instructions, then search for Pub 1075, then search for Exhibit 7 within Pub 1075) and the *Michigan Department of Treasury Safeguard Requirements of Confidential Data* (Contact Brenda Lindsay 517-636-4084 or Rich Grandy 517-636-4085 for current version of document) must be included in the Contract. The language in both documents is not modifiable, although requirements may be added.]

The Contractor must comply with the requirements of *IRS Publication 1075* (including *Exhibit 7 Safeguarding Contract Language*) and *Michigan Department of Treasury Safeguard Requirements of Confidential Tax Data*.

5. Project Management

5.1. Project Plan

[**Read and delete:** Identify required project management processes, including expected frequency and mechanisms for updates and progress reviews, and individuals responsible for receiving and responding to the requested information. Provide details about the project plan and how it will be managed or ask the Contractor to propose a project plan. Project plan should identify items such as the required contact personnel; the date the project plan must be submitted to the State; project management process; project breakdown identifying sub-projects, tasks, and resources required; expected frequency and mechanisms for updates/progress reviews; process for addressing issues/changes; and individuals responsible for receiving/reacting to the requested information.]

The Contractor will carry out this project under the direction and control of the Program Manager. Within 30 calendar days of the Effective Date, the Contractor must submit a project plan to the Program Manager for final approval. The plan must include: (a) the Contractor's organizational chart with names and title of personnel assigned to the project, which must align with the staffing stated in accepted proposals; and (b) the project breakdown showing sub-projects, tasks, and resources required.

5.2. Meetings

The Contractor must attend the following meetings:

SCHEDULE A – STATEMENT OF WORK CONTRACT ACTIVITIES

~~[**Read and delete:** Insert the meetings that will be required under any resulting Contract, e.g. Kick-off meeting within 30 calendar days of the Effective Date.]~~

~~The State may request other meetings, as it deems appropriate.~~
~~**Reporting** The Contractor must submit, to the [Program Manager or identify the individual(s) the reports should be delivered to], the following written reports: [Identify the type and frequency of reports required.]~~

~~The Contractor must explain its reporting capabilities and any reporting that is included in its proposal. In addition, provide samples of required reports as attachments to this RFP.~~

~~6.~~5. Pricing

~~6.1.~~5.1. Price Term

Pricing is firm for the entire length of the Contract.

~~(OR)~~

~~Pricing is firm for a 365-day period ("Pricing Period"). The first pricing period begins on the Effective Date. Adjustments may be requested, in writing, by either party and will take effect no earlier than the next Pricing Period.~~

~~6.2.~~5.2. Price Changes

Adjustments will be based on changes in actual Contractor costs. Any request must be supported by written evidence documenting the change in costs. The State may consider sources, such as the Consumer Price Index; Producer Price Index; other pricing indices as needed; economic and industry data; manufacturer or supplier letters noting the increase in pricing; and any other data the State deems relevant.

Following the presentation of supporting documentation, both parties will have 30 days to review the information and prepare a written response. If the review reveals no need for modifications, pricing will remain unchanged unless mutually agreed to by the parties. If the review reveals that changes are needed, both parties will negotiate such changes, for no longer than 30 days, unless extended by mutual agreement.

The Contractor remains responsible for Contract Activities at the current price for all orders received before the mutual execution of a Change Notice indicating the start date of the new Pricing Period.

~~7.~~6. Ordering

~~7.1.~~6.1. Authorizing Document

The appropriate authorizing document for the Contract will be [**Read and Delete:** Insert the appropriate authorizing document (e.g. purchase order, delivery order, master agreement]].

~~8.~~7. Invoice and Payment

~~8.1.~~7.1. Invoice Requirements

[**Read and delete:** Use either the invoice language defined in the **Terms of Payment** section of the *Standard Contract Terms* or define a different process in this section.]

SCHEDULE A – STATEMENT OF WORK CONTRACT ACTIVITIES

All invoices submitted to the State must include: (a) date; (b) purchase order; (c) quantity; (d) description of the Contract Activities; (e) unit price; (f) shipping cost (if any); and (g) total price. Overtime, holiday pay, and travel expenses will not be paid.

~~8.2.~~7.2. Payment Methods

The State will make payment for Contract Activities [**Read and Delete:** Identify the appropriate payment method(s) (e.g., EFT or, if approved by the Chief Procurement Officer, PCard).]

~~8.3.~~7.3. Procedure

[**Read and Delete*:* Include this section as appropriate.** Identify specific requirements such as the procedure for submitting invoices and where/how they are submitted (e.g. to program manager; through CHAMPS)]

~~**9. Liquidated Damages**~~

~~[**Read and Delete:** Legislation and policy requires that multi-year contracts include either Liquidated Damages or Service-Level Agreements. Determine which is most appropriate for this solicitation. Dollars must be reasonable in relation to the possible damages suffered by a triggering event and not unconscionable or excessive. See suggested language for late or improper completion of work below. The dollar values must be modified to fit the project.]~~

~~Late or improper completion of the Contract Activities will cause loss and damage to the State and it would be impracticable and extremely difficult to fix the actual damage sustained by the State. Therefore, if there is late or improper completion of the Contract Activities the State is entitled to collect liquidated damages in the amount of $5,000 and an additional $100 per day for each day Contractor fails to remedy the late or improper completion of the Work.~~

~~**10. Service-Level Agreements (SLAs)**~~

~~[**Read and Delete:** Legislation and policy requires that multi-year contracts include either Liquidated Damages or Service-Level Agreements. Determine which is most appropriate for this solicitation.~~

~~A service-level agreement (SLA) defines the level of service you expect from a vendor, laying out how service is measured, as well as remedies should the agreed-upon service levels not be achieved.~~

- ~~SLAs are statements that identify specifications and performance levels that if not met, may require the contractor to provide financial compensation to the state for non-performance.~~
- ~~SLAs clearly define metrics, responsibilities and expectations so that, in the event of issues with the service, neither party can plead ignorance.~~
- ~~Service Level Agreements are required for category 4 and 5 contracts and recommended for category 3 contracts.~~

Contractor must enter company name here

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SCHEDULE A – STATEMENT OF WORK CONTRACT ACTIVITIES

- The SLA's in the table below are an example. Other examples include timely reporting, reporting accuracy, timely response time, call center response time, etc. Each SLA should reference the coordinating section in the SOW that indicates that requirement.

A. The Contractor will be held accountable to meet the requirements and the service level requirements established in this Contract.

B. The State reserves the right to reconsider or amend SLA amounts for split awards should they occur.

C. Please Note: Should Contractors have any questions or requirement clarification with regard to the SLAs, they should submit them during the *Question and Answer Period* of this solicitation, please see the **Proposal Instructions** for the timeline.

Service Level Agreements for this Contract will be as follows:

[Read and delete: Modify the example below to meet the needs of your specific project]

SLA Metric 1: Timely Deliveries	
Definition and Purpose	All orders must be delivered within X calendar days of receipt of order. AND/OR The Contractor must ensure that items and quantities delivered are exactly the items, brands, and quantities on the Order Confirmation. No substitutions will be allowed without prior written permission by Program Manager and a Change Notice executed by the Contract Administrator. The entire order will be received on the same day unless a partial delivery has been approved in advance by the Program Manager.
Acceptable Standard	1. All deliveries must occur in accordance with the approved delivery schedule for each Facility and Facility Receiving hours. See Section x.x. 2. Extenuating circumstances must be communicated by the Contractor to the Program Manager prior to the scheduled delivery date and time. 3. Items, brands, and quantities delivered will match the Order Confirmation exactly.

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SCHEDULE A – STATEMENT OF WORK CONTRACT ACTIVITIES

SLA Metric 1. Timely Deliveries	
	4. Signed and dated packing slips will be provided to Agency name at the time of delivery. 5. The entire order must be delivered on the same day unless a partial delivery has been approved in advance by the Program Manager. 6. Orders not received in their entirety, as determined by a review of the Data Sources, will be considered inaccurate. The acceptable standard is 100% compliance
Credit Due for Failing to Meet the Service Level Agreements	1. $100.00 may be assessed for each of the first five occurrences of non-compliance in a given calendar year. 2. $500.00 may be assessed beginning with the sixth occurrence of non-compliance and on each occurrence thereafter in a given calendar year. Extenuating circumstances will be reviewed by the Program Manager before any Service Credits are assessed. At the discretion of the State, these credits may be applied toward any payable due to the Contractor or be payable directly to the State. Payments made directly to the state will be completed within 10 days of notice of assessment.

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